

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

WYETH,)	
)	
)	
Plaintiff,)	
)	Civil Action No.: 06-222 JJF
v.)	
)	PUBLIC VERSION
IMPAX LABORATORIES, INC.,)	
)	
Defendant.)	
_____)	

**DECLARATION OF MARY B. MATTERER IN SUPPORT OF
IMPAX'S MOTION TO MODIFY THE SCHEDULING ORDER
AND MOTION TO COMPEL**

RICHARD K. HERRMANN (I.D. No. 405)
MARY B. MATTERER (I.D. No. 2696)
MORRIS JAMES HITCHENS & WILLIAMS LLP
222 Delaware Ave., 10th Floor
Wilmington, DE 19801
Telephone: (302) 888-6800
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M. PATRICIA THAYER (*pro hac vice*)
JOHN M. BENASSI (*pro hac vice*)
JESSICA R. WOLFF (*pro hac vice*)
DANIEL KASSABIAN (*pro hac vice*)
SAMUEL F. ERNST (*pro hac vice*)
HELLER EHRMAN LLP
4350 La Jolla Village Drive, 7th Floor
San Diego, CA 92101
Telephone: (858) 450-8400
Facsimile: (858) 450-8499

Attorneys for Defendant
IMPAX LABORATORIES, Inc.

Originally filed: August 10, 2006
Public version filed: August 15, 2006

I, Mary B. Matterer, declare:

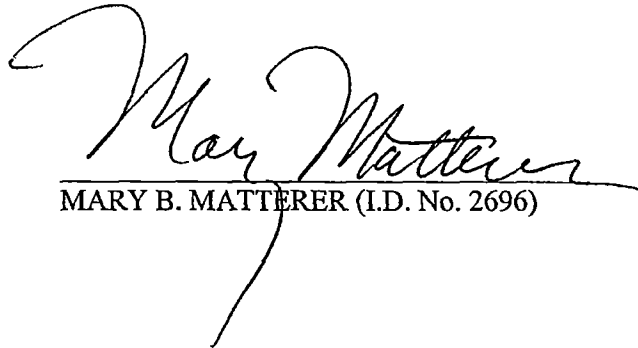
1. I am a partner at the law firm of Morris, James, Hitchens & Williams LLP, counsel to Defendant Impax Laboratories, Inc. ("Impax") in this matter.
2. Attached hereto as Exhibit 1 is a copy of a letter from Impax to Plaintiff Wyeth mailed on February 21, 2006.
3. Attached hereto as Exhibit 2 is a copy of an excerpt from U.S. Patent Application No. 60/014,006.
4. Attached hereto as Exhibit 3 is a copy of the article "Once-Daily Venlafaxine Extended Release (XR) and Venlafaxine Immediate Release (IR) in Outpatients with Major Depression" by Lynn A. Cunningham, M.D., appearing in *Annals of Clinical Psychiatry*, Vol. 9, No. 3 (1997).
5. Attached hereto as Exhibit 4 is a copy of the Order of March 23, 2005 of the Honorable Magistrate Judge Patty Shwartz in *Wyeth v. Teva Pharmaceutical USA, Inc. and Teva Pharmaceutical Industries Ltd.*, Civil Action No. 03-1293 (FSH) in the United States District Court for the District of New Jersey.
6. Attached hereto as Exhibit 5 is a copy of Impax's First Set of Requests for Production (Nos. 1-4) served June 23, 2006.
7. Attached hereto as Exhibit 6 is a copy of Impax's Second Set of Requests for Production (Nos. 5-86) served June 30, 2006.
8. Attached hereto as Exhibit 7 is a copy of Plaintiff's Responses and Objections to Impax's First Request for Production of Documents and Things (Nos. 1-4) served July 26, 2006.

9. Attached hereto as Exhibit 8 is a copy of Plaintiff's Responses and Objections to Impax's Second Request for Production of Documents and Things (Nos. 5-86) served July 31, 2006.
10. Attached hereto as Exhibit 9 is a copy of an August 3, 2006 letter from Linda A. Wadler to Daniel N. Kassabian.
11. Attached hereto as Exhibit 10 is a copy of a July 24, 2006 letter from Daniel N. Kassabian to Linda A. Wadler.
12. Attached hereto as Exhibit 11 is a copy of a July 14, 2006 letter from Linda A. Wadler to Jessica R. Wolff and Daniel N. Kassabian.
13. Attached hereto as Exhibit 12 is a copy of a August 3, 2006 letter from Linda A. Wadler to Daniel N. Kassabian.
14. Attached hereto as Exhibit 13 is a copy of a July 31, 2006 letter from Daniel N. Kassabian to Linda A. Wadler.
15. Attached hereto as Exhibit 14 is a copy of a July 26, 2006 letter from Linda A. Wadler to Jessica R. Wolff and Daniel N. Kassabian.
16. Attached hereto as Exhibit 15 is a copy of an August 2, 2006 letter from Linda A. Wadler to Samuel Ernst.
17. Attached hereto as Exhibit 16 is a copy of an August 1, 2006 letter from Linda A. Wadler to Daniel N. Kassabian.
18. Attached hereto as Exhibit 17 is a copy of an August 1, 2006 letter from Mary B. Matterer to Henry C. Dinger.
19. Attached hereto as Exhibit 18 is a copy of an August 4, 2006 letter from Henry C. Dinger to Mary B. Matterer.

20. Attached hereto as Exhibit 19 is a copy of a July 31, 2006 letter from Samuel Ernst to Linda A. Wadler.
21. Attached hereto as Exhibit 20 is a copy of the Certification of Michael E. Patunas, filed on June 2, 2005 in *Wyeth v. Teva Pharmaceutical USA, Inc. and Teva Pharmaceutical Industries Ltd.*, Civil Action No. 03-1293 (FSH) in the United States District Court for the District of New Jersey.
22. Attached hereto as Exhibit 21 is a copy of an August 4, 2006 letter from Samuel Ernst to Linda A. Wadler.
23. Attached hereto as Exhibit 22 is a copy of an August 4, 2006 letter from Robert A. Pollock to Daniel N. Kassabian.
24. Attached hereto as Exhibit 23 is a copy of an August 8, 2006 letter from Robert A. Pollock to Daniel N. Kassabian.
25. Attached hereto as Exhibit 24 is a copy of an August 4, 2006 letter from Daniel N. Kassabian to Linda A. Wadler.
26. Attached hereto as Exhibit 25 is a copy of an August 7, 2006 letter from Samuel Ernst to Linda A. Wadler.
27. Attached hereto as Exhibit 26 is a copy of the Stipulation and Protective Order entered on January 14, 2004 in *Wyeth v. Teva Pharmaceutical USA, Inc. and Teva Pharmaceutical Industries Ltd.*, Civil Action No. 03-1293 (FSH) in the United States District Court for the District of New Jersey.
28. Attached hereto as Exhibit 27 is a copy of the amendments to the Federal Rules of Civil Procedure governing electronic discovery, approved by the Supreme Court on April 12, 2006 to take effect on December 31, 2006.

29. Attached hereto as Exhibit 28 is a copy of the May 16, 1996 cover letter from NDA 20-699.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct and that this declaration was executed on this tenth day of August, 2006 at Wilmington, Delaware.



MARY B. MATTERER (I.D. No. 2696)

CERTIFICATE OF SERVICE

I hereby certify that on the 15th day of August, 2006, I electronically filed the foregoing document, **PUBLIC VERSION OF DECLARATION OF MARY B. MATTERER IN SUPPORT OF IMPAX'S MOTION TO MODIFY THE SCHEDULING ORDER AND MOTION TO COMPEL**, with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

Jack B. Blumenfeld
Karen Jacobs Loudon
Morris Nichols Arsht & Tunnell
1201 N. Market Street
Wilmington, DE 19801

Additionally, I hereby certify that on the 15th day of August, 2006, the foregoing document was served as indicated on the following:

VIA EMAIL AND HAND DELIVERY

Jack B. Blumenfeld
Karen Jacobs Loudon
Morris Nichols Arsht & Tunnell
1201 N. Market Street
Wilmington, DE 19801

VIA EMAIL AND FEDERAL EXPRESS

Basil J. Lewris
Linda A. Wadler
Finnegan Henderson Farabow
Garrett & Dunner
901 New York Avenue, NW
Washington, DE 20001
202.408.4000
Bill.Lewris@finnegan.com
Linda.Wadler@finnegan.com

/s/ Mary B. Matterer

Mary B. Matterer (I.D. No. 2696)
Morris James Hitchens & Williams LLP
222 Delaware Avenue, 10th Floor
Wilmington, DE 19801
(302) 888-6800
mmatterer@morrisjames.com

Attorneys for IMPAX LABORATORIES, INC.

EXHIBIT 1



30831 Huntwood Avenue Hayward, CA 94544
Phone (510) 476-2000 Fax (510) 476-2092

February 21, 2006

Via Federal Express

Wyeth Worldwide Headquarters
Attn.: Legal Department
Five Giralda Farms
Madison, New Jersey 07940

Tracking #8527 7076 2767

Wyeth Pharmaceuticals Worldwide Headquarters
Attn.: Legal Department
500 Arcola Road
Collegeville, Pennsylvania 19426

Tracking #8527 7076 2778

Re: Venlafaxine Hydrochloride Extended Release Capsule Notice Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 regarding U.S. Patent Nos. 6,274,171; 6,419,958; and 6,403,120

Dear Sir or Madam:

I am writing pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 to inform you that Impax Laboratories, Inc. ("Impax") submitted to the United States Food and Drug Administration an Abbreviated New Drug Application ("ANDA") under 21 U.S.C. § 355(j)(1) and (2)(A), and 21 C.F.R. § 314.94. The ANDA was submitted in order to obtain approval to engage in the commercial manufacture, use, or sale of Venlafaxine Hydrochloride Extended Release Capsules, provided in 37.5 mg, 75 mg and 150 mg dosage strengths.

The Application has been assigned ANDA 78-057 and contains any required bioavailability or bioequivalence data or information.

Impax Laboratories, Inc. intends to market its product before the expiration of U.S. Patent Nos. 6,274,171, 6,419,958 and 6,403,120 (hereinafter "the '171, the '958, and the '120 patents"). All three patents expire on March 17, 2017, but have pediatric exclusivities expiring on September 20, 2017. As required by 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), the ANDA includes a certification which states that, in Impax's opinion and to the best of its knowledge, the '171, the '958 and the '120 patents are not infringed, are invalid and/or are unenforceable.

As required by 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95, a detailed statement of the factual and legal basis for Impax's opinion that the '171, the '958 and the '120 patents are not infringed by our venlafaxine product is attached. Impax reserves the right to assert invalidity or unenforceability of the patents, as well as additional non-infringement arguments, in any litigation commenced against it asserting patent infringement of the '171, the '958 or the '120 patent claims.

Permission to use Federal Express for delivery of this notice and detailed statement was granted by Martin Shimer of the Office of Generic Drugs on February 9, 2006.

Sincerely,
IMPAX Laboratories, Inc.



Mark C. Shaw
Vice-President, Regulatory Affairs and Compliance

Enclosure: Detailed Statement

**IMPAX'S DETAILED STATEMENT OF THE FACTUAL AND LEGAL BASES FOR ITS OPINION
THAT U.S. PATENT NOS. 6,274,171, 6,419,958, AND 6,403,120 ARE INVALID,
UNENFORCEABLE OR NOT INFRINGED BY THE MANUFACTURE, USE OR SALE OF IMPAX
LABORATORIES, INC.'S 37.5 MG, 75 MG, OR 150 MG VENLAFAXINE HYDROCHLORIDE
EXTENDED-RELEASE CAPSULES**

A. Impax's venlafaxine HCl Extended Release Product Does Not Contain Microcrystalline Cellulose.

Impax's venlafaxine HCl extended release formulation does not contain microcrystalline cellulose. Our product is a capsule containing sugar spheres coated with a layer of venlafaxine hydrochloride, which is covered with a sustained-release coating. It is not prepared using a spheronization process.

B. There is No Literal Infringement Because Impax's Product Does Not Contain Microcrystalline Cellulose.

The '171 patent contains eight independent and 17 dependent claims. All of the dependent claims are ultimately dependent on claim 1. Claims 1 and 19 are independent claims directed to an extended release formulation that expressly require that each formulation contain at least 50% microcrystalline cellulose. Independent claims 20-25 are generally directed to a method providing certain peak blood plasma levels by administering venlafaxine hydrochloride in certain extended release formulations.

The '958 patent contains six independent claims. Like claims 20-25 of the '171 patent, all six claims of the '958 patent are generally directed to a method of providing certain peak blood plasma levels by administering venlafaxine hydrochloride in certain extended release formulations.

The '120 patent contains one independent and 13 dependent claims. These claims are also method claims generally directed to a method of providing therapeutic peak blood plasma levels of venlafaxine by administering certain extended release formulations.

All of the claims of the '171, '958, and '120 patents either explicitly require that the extended release formulation includes microcrystalline cellulose or implicitly require that the extended release formulation includes one or more additional components to provide the claimed extended release profile.

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Wyeth Pharmaceuticals Worldwide Headquarters
February 21, 2006
Page 2

All of the claims use the phrase "extended release formulation" in the body of the claim. This phrase should be interpreted to mean a formulation comprising venlafaxine hydrochloride and at least microcrystalline cellulose. In reviewing the specification of the patents, it is apparent that applicants defined "extended release formulation" to require microcrystalline cellulose:

The formulations of this invention comprise an extended release formulation of venlafaxine hydrochloride comprising ... spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and, optionally,

'171 patent, col. 2, lines 14-18 (emphasis added).

Applicants consistently used this definition to define their invention. In the Detailed Description of the Invention, applicants stated:

The extended release formulations of this invention are comprised of [venlafaxine hydrochloride] in a mixture with microcrystalline cellulose and hydroxypropyl methylcellulose.

'171 patent, col. 2, line 63 – col. 3, line 2 (emphasis added).

The Abstracts of the patents also define the invention as requiring microcrystalline cellulose:

More particularly, the invention comprises an extended release formulation of venlafaxine hydrochloride comprising ... venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and, optionally,

'171 patent, Abstract (emphasis added).

Furthermore, the specifications only discuss the preparation of spheroids containing microcrystalline cellulose.

Numerous spheroid formulations were prepared using different grades of microcrystalline cellulose and hydroxypropylmethylcellulose

'171 patent, col. 5, lines 1-3. See, also, Examples 1-7.

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Wyeth Pharmaceuticals Worldwide Headquarters
February 21, 2006
Page 3

From the specifications, it is also clear that applicants were not intending to include all possible excipients because they argued the superiority of the extended release formulation with microcrystalline cellulose compared to extended release tablets using hydrogel technology.

Numerous attempts to produce extended release tablets by hydrogel technology proved to be fruitless

'171 patent, col. 4, lines 60-64.

Finally, it is significant that Wyeth has already litigated the construction of the phrase "extended release formulation" in Wyeth v. Teva Pharmaceuticals USA, Inc., et al., U.S. District Court for the District of New Jersey, Case No. 2:03-cv-01293-WJM-RJH. In the face of Wyeth's arguments for a broader construction, the District Court ruled that the term "extended release formulation" means:

[A] formulation comprising venlafaxine hydrochloride, microcrystalline cellulose and, optionally HPMC coated with a mixture of ethyl cellulose and HPMC in an amount needed to provide a specific unit dosage administered once-a-day to provide a therapeutic blood plasma level of venlafaxine over the entire 24-hour period of administration.

Markman Order, p. 1 (emphasis added).

After receiving the above claim construction order, Wyeth settled with Teva. Furthermore, nothing in the prosecution histories contradicts this interpretation of the claimed invention as requiring microcrystalline cellulose.

Because Impax's venlafaxine extended release formulation does not contain microcrystalline cellulose, it does not literally infringe any of the claims of the '171, the '958, and the '120 patents.

C. There is No Infringement Under the Doctrine of Equivalents Because a Required Element is Completely Missing from Impax's Extended Release Formulation.

To infringe under the Doctrine of Equivalents, Impax's formulation would have to include every claim limitation, or its equivalent. A claim limitation is equivalently present only if there are insubstantial differences between the claim limitation and the corresponding aspect of the accused product. Thus, the Doctrine of Equivalents allows

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Wyeth Pharmaceuticals Worldwide Headquarters
February 21, 2006
Page 4

the patent to claim those "unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 733 (2002) (emphasis added).

A key limitation to the application of the Doctrine of Equivalents is the "All Elements Rule." The Doctrine of Equivalents does not apply if applying the doctrine would vitiate an entire claim limitation.

Impax's extended release formulation has no microcrystalline cellulose, a critical excipient that forms the structure that is coated to provide the extended release profile claimed. Thus, expanding the claims of the patents to cover all products providing the extended release profile, irrespective of whether they contain microcrystalline cellulose, would impermissibly eliminate the critical excipient element in its entirety.

Moreover, the venlafaxine-coated sugar spheres used by Impax are not an insubstantial change. Whereas, the microcrystalline cellulose is critical to the formulation described in the '171, '958 and '120 patents, there is no component of the Impax formulation that serves a similar function because the formulation and process used is completely different.

In conclusion, Impax's venlafaxine HCl extended release formulation containing sugar spheres lacks microcrystalline cellulose, a required element, and therefore does not infringe any claim of the '171, the '958 and the '120 patents, either literally or under the doctrine of equivalents.

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From **IMPAX LABORATORIES**
Date **2/21/06** Sender's FedEx Account Number **1906-6067-2**Sender's Name **St Skarranga** Phone **(510) 476-2000**Company **IMPAX LABORATORIES**Address **30831 HUNTHOOD AVE**City **HAYWARD** State **CA** Zip **94544-7003**Your Internal Billing Reference **OPTIONAL**To Recipient's Name **Legal Dept** Phone **973 660-5000**Company **Wyeth Worldwide Headquarters**Recipient's Address **5 Giraldi Farms**City **Madison** State **NJ** Zip **07940**Try online shipping at fedex.comQuestions? Visit our Web site at fedex.com
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Company IMPAX LABORATORIES

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City HAYWARD State CA ZIP 94544-7003

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Company Myeth Pharmaceuticals Worldwide Headquarters

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City Collegeville State PA ZIP 19326

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4. Insurance
☐ Insured ☐ Insured ☐ Insured
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5. Signature
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14. Total Weight 10.00 lbs. Total Dimensions 10x10x10 inches

15. Total Value \$100.00

16. Signature of Shipper [Signature]

17. Signature of Addressee [Signature]

18. Date 3/21/06

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95. Signature of Addressee [Signature]

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106. Signature of Shipper [Signature]

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108. Date 3/21/06

109. Time 10:00 AM

110. Total Weight 10.00 lbs. Total Dimensions 10x10x10 inches

111. Total Value \$100.00

112. Signature of Shipper [Signature]

113. Signature of Addressee [Signature]

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136. Signature of Shipper [Signature]

137. Signature of Addressee [Signature]

138. Date 3/21/06

139. Time 10:00 AM

140. Total Weight 10.00 lbs. Total Dimensions 10x10x10 inches

141. Total Value \$100.00

142. Signature of Shipper [Signature]

143. Signature of Addressee [Signature]

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EXHIBIT 2



EXTENDED RELEASE FORMULATION



Background of the invention

5 Extended release drug formulations are conventionally produced as compressed tablets by hydrogel tablet technology. To produce these sustained release tablet drug dosage forms, the active ingredient is conventionally compounded with cellulose ethers such as methyl cellulose, ethyl cellulose or hydroxypropylmethylcellulose with or without other excipients and the resulting mixture is pressed into tablets. When the tablets are orally
 10 administered, the cellulose ethers in the tablets swell upon hydration from moisture in the digestive system, thereby limiting exposure of the active ingredient to moisture. As the cellulose ethers are gradually leached away by moisture, water more deeply penetrates the gel matrix and the active ingredient slowly dissolves and diffuses through the gel, making it available for absorption by the body. An example of such a sustained release dosage form
 15 of the analgesic/antiinflammatory drug etodolac (Lodine®) appears in US patent 4,966,768.

Where the production of tablets is not feasible, it is conventional in the drug industry to prepare encapsulated drug formulations which provide extended or sustained release properties. In this situation, the extended release capsule dosage forms may be
 20 formulated by mixing the drug with one or more binding agents to form a uniform mixture which is then moistened with water or a solvent such as ethanol to form an extrudable plastic mass from which small diameter, typically 1 mm, cylinders of drug/matrix are extruded, chopped into appropriate lengths and transformed into spheroids using standard spheronization equipment. The spheroids, after drying, may then be film-coated to retard
 25 dissolution. Gelatin capsules are filled with the film-coated spheroids in the quantity needed to obtain the desired therapeutic effect. Spheroids releasing the drug at different rates may be combined in a gelatin capsule to obtain desired release rates and blood levels. US patent 4,138,475 discloses a sustained release pharmaceutical composition consisting of a hard gelatin capsule filled with film-coated spheroids comprised of propranolol in
 30 admixture with microcrystalline cellulose wherein the film coating is composed of ethyl cellulose, optionally with hydroxypropylmethylcellulose and/or a plasticizer.

Venlafaxine, 1-[2-(dimethylamino)-1-(4-methoxyphenyl)ethyl]cyclohexanol, is an important drug in the neuropharmacological arsenal used for treatment of depression. Venlafaxine and the acid addition salts thereof are disclosed in US patent 4,535,186.
 35 Venlafaxine hydrochloride is presently administered to adults in compressed tablet form in doses ranging from 75 to 350 mg/day, in divided doses two or three times a day. In therapeutic dosing with venlafaxine hydrochloride tablets, rapid dissolution results in a

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rapid increase in blood plasma levels of the active compound shortly after administration followed by a decrease in blood plasma levels over several hours as the active compound is eliminated or metabolized, until sub-therapeutic plasma levels are approached after about twelve hours following administration, thus requiring additional dosing with the drug.

- 5 With the plural daily dosing regimen, the most common side effect is nausea, experienced by about forty five percent of patients under treatment with venlafaxine hydrochloride. Vomiting also occurs in about seventeen percent of the patients.

10

Brief Description of the Invention

In accordance with this invention, there is provided an extended release (ER), encapsulated formulation containing venlafaxine hydrochloride as the active drug component, which provides in a single dose, a therapeutic blood serum level over a twenty
15 four hour period.

- Through administration of the venlafaxine formulation of this invention, there is provided a method for obtaining a flattened drug plasma concentration to time profile, thereby affording a tighter plasma therapeutic range control than can be obtained with multiple daily dosing. In other words, this invention provides a method for eliminating the
20 sharp peaks and troughs (hills and valleys) in blood plasma drug levels induced by multiple daily dosing with conventional immediate release venlafaxine hydrochloride tablets. In essence, the plasma levels of venlafaxine hydrochloride rise, after administration of the extended release formulations of this invention, for between about five to about eight hours (optimally about six hours) and then begin to fall through a protracted, substantially linear
25 decrease from the peak plasma level for the remainder of the twenty four hour period, maintaining at least a threshold therapeutic level of the drug during the entire twenty-four period. In contrast, the conventional immediate release venlafaxine hydrochloride tablets give peak blood plasma levels in 2 to 4 hours. Hence, in accordance with the use aspect of this invention, there is provided a method for moderating the plural blood plasma peaks and
30 valleys attending the pharmacokinetic utilization of multiple daily tablet dosing with venlafaxine hydrochloride which comprises administering to a patient in need of treatment with venlafaxine hydrochloride, a one-a-day, extended release formulation of venlafaxine hydrochloride.

- The use of the one-a-day venlafaxine hydrochloride formulations of this invention
35 reduces by adaptation, the level of nausea and incidence of emesis that attend the administration of multiple daily dosing. In clinical trials of venlafaxine hydrochloride ER,

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the probability of developing nausea in the course of the trials was greatly reduced after the first week. Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies. Thus, in accordance with this use aspect of the invention there is provided a method for reducing the level of nausea and incidence of emesis attending the administration of venlafaxine hydrochloride which comprises dosing a patient in need of treatment with venlafaxine hydrochloride with an extended release formulation of venlafaxine hydrochloride once a day in a therapeutically effective amount.

Detailed Description of the Invention

1-[2-(dimethylamino)-1-(4-methoxyphenyl)ethyl]cyclohexanol hydrochloride is polymorphic. Of the forms isolated and characterized to date, Form I is considered to be the kinetic product of crystallization which can be converted to Form II upon heating in the crystallization solvent. Forms I and II cannot be distinguished by their melting points but do exhibit some differences in their infrared spectra and X-ray diffraction patterns. Any of the polymorphic forms such as Form I or Form II may be used in the formulations of the present invention.

The extended release formulations of this invention are comprised of 1-[2-(dimethylamino)-1-(4-methoxyphenyl)ethyl] cyclohexanol hydrochloride in admixture with microcrystalline cellulose and hydroxypropylmethylcellulose. Formed as beads or spheroids, the drug containing formulation is coated with a mixture of ethyl cellulose and hydroxypropylmethyl cellulose to provide the desired level of coating, generally from about two to about twelve percent on a weight/weight basis of final product or more preferably from about five to about ten percent (w/w), with best results obtained at from about 6 to about 8 percent (w/w). More specifically, the extended release spheroid formulations of this invention comprise from about 30 to 40 percent venlafaxine hydrochloride, from about 50 to about 70 percent microcrystalline cellulose, NF, from about 0.25 to about 1 percent hydroxypropylmethylcellulose, USP, and from about 5 to about 10 percent film coating, all on a weight/weight basis. And preferably, the spheroid formulations contain about 35 percent venlafaxine hydrochloride, about 55 to 60 percent microcrystalline cellulose NF (Avicel® PH101), about one half percent hydroxypropyl methylcellulose 2208 USP (K3, Dow, which has a viscosity of 3 cps for 2% aqueous solutions, a methoxy content of 19–24% and a hydroxypropoxy content of 4–13%), and from about 6 to 8 percent film coating.

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The film coating is comprised of 80 to 90 percent of ethyl cellulose, NF and 10 to 20 percent hydroxypropyl methylcellulose (2910), USP on a weight/weight basis. Preferably the ethyl cellulose has a methoxy content of 44.0-51% and a viscosity of 50 cps for a 5% aqueous solution and the hydroxypropylmethylcellulose is USP 2910 having a
5 viscosity of 6 cps at 2% aqueous solution with a methoxy content of 28-30% and a hydroxypropoxy content of 7-12%. The ethyl cellulose used herein is Aqualon HG 2834.

Other equivalents of the hydroxypropylmethylcelluloses 2208 and 2910 USP and ethyl cellulose, NF, having the same chemical and physical characteristics as the proprietary products named above may be substituted in the formulation without changing
10 the inventive concept.

It was completely unexpected that an extended release formulation containing venlafaxine hydrochloride could be obtained because the hydrochloride of venlafaxine proved to be extremely water soluble. Numerous attempts to produce extended release tablets by hydrogel technology proved to be fruitless because the compressed tablets were
15 either physically unstable (poor compressibility or capping problems) or dissolved too rapidly in dissolution studies. Typically, the tablets prepared as hydrogel sustained release formulations gave 40-50% dissolution at 2 hrs, 60-70% dissolution at 4 hrs and 85-100% dissolution at 8 hrs.

Numerous spheroid formulations were prepared using different grades of
20 microcrystalline cellulose and hydroxypropyl methylcellulose, different ratios of venlafaxine hydrochloride and filler, different binders such as polyvinylpyrrolidone, methylcellulose, water, and polyethylene glycol of different molecular weight ranges in order to find a formulation which would provide a suitable granulation mix which could be extruded properly. In the extrusion process, heat buildup occurred which dried out the
25 extrudate so much that it was difficult to convert the extruded cylinders into spheroids. Addition of hydroxypropylmethylcellulose 2208 to the venlafaxine hydrochloride-microcrystalline cellulose mix made production of spheroids practical.

The following examples are presented to illustrate applicant's solution to the problem of preparation of the extended release drug containing formulations of this
30 invention.

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Example 1.

VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE CAPSULES

A mixture of 44.8 parts (88.4 % free base) of venlafaxine hydrochloride, 74.6 parts of the microcrystalline cellulose, NF, and 0.60 parts of hydroxypropylmethyl
5 cellulose 2208, USP, are blended with the addition of 41.0 parts water. The plastic mass of material is extruded, spheronized and dried to provide uncoated drug containing spheroids.

Stir 38.25 parts of ethyl cellulose, NF, HG2834 and 6.75 parts of hydroxypropyl methylcellulose 2910, USP in a 1:1 v/v mixture of methylene chloride and anhydrous
10 methanol until solution of the film coating material is complete.

To a fluidized bed of the uncoated spheroids is applied 0.667 parts of coating solution per part of uncoated spheroids to obtain extended release, film coated spheroids having a coating level of 3%.

The spheroids are sieved to retain the coated spheroids of a particle size between
15 0.85 mm to 1.76 mm diameter. These selected film coated spheroids are filled into hard gelatin capsules conventionally.

Example 2.

Same as for Example 1 except that 1.11 parts of the film coating solution per part of
20 uncoated spheroids is applied to obtain a coating level of 5%.

Example 3.

Same as for Example 1 except that 1.33 parts of the film coating solution is applied to 1 part of uncoated spheroids to obtain a coating level of 6%.

25

Example 4.

Same as for Example 1 except that 1.55 parts of the film coating solution is applied to 1 part of uncoated spheroids to obtain a coating level of 7%.

30 The test for acceptability of the coating level is determined by analysis of the dissolution rate of the finished coated spheroids prior the encapsulation. The dissolution procedure followed uses USP Apparatus 1 (basket) at 100 rpm in purified water at 37°C. Conformance with the dissolution rate given in Table 1 provides the twenty-four hour therapeutic blood levels for the drug component of the extended release capsules of this
35 invention in capsule form. Where a given batch of coated spheroids releases drug too slowly to comply with the desired dissolution rate study, a portion of uncoated spheroids

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or spheroids with a lower coating level may be added to the batch to provide, after thorough mixing, a loading dose for rapid increase of blood drug levels. A batch of coated spheroids that releases the drug too rapidly can receive additional film-coating to give the desired dissolution profile.

Table 1

Acceptable Coated Spheroid Dissolution Rates

<u>Time (hours)</u>	<u>Average % Venlafaxine HCl released</u>
2	<30
4	30-55
8	55-80
12	65-90
24	>80

Batches of the coated venlafaxine hydrochloride containing spheroids which have a dissolution rate corresponding to that of Table 1 are filled into hard gelatin capsules in an amount needed to provide the unit dosage level desired. The standard unit dosage immediate release (IR) tablet used presently provides amounts of venlafaxine hydrochloride equivalent to 25 mg, 37.5 mg, 50 mg, 75 mg and 100 mg venlafaxine. The capsules of this invention are filled to provide an amount of venlafaxine hydrochloride equivalent to that presently used in tablet form and also up to about 150 mg venlafaxine hydrochloride.

Dissolution of the venlafaxine hydrochloride ER capsules is determined as directed in the U. S. Pharmacopoeia (USP) using apparatus 1 at 100 rpm on 0.9 L of water. A filtered sample of the dissolution medium is taken at the times specified. The absorbance of the clear solution is determined from 240 to 450 nanometers (nm) against the dissolution medium. A baseline is drawn from 450 nm through 400 nm and extended to 240 nm. The absorbance at the wavelength of maximum absorbance (about 274 nm) is determined with respect to this baseline. Six hard gelatin capsules are filled with the theoretical amount of venlafaxine hydrochloride spheroids and measured for dissolution. Standard samples consist of venlafaxine hydrochloride standard solutions plus a gelatin capsule correction solution. The percentage of venlafaxine released is determined from the equation

$$\% \text{ Venlafaxine hydrochloride released} = \frac{(As)(Wr)(S)(V1)(0.888)(100)}{(Ar)(V2)(C)}$$

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where A_s is absorbance of sample preparation, W_r is weight of reference standard, mg; S is strength of the reference standard, decimal; V_1 is the volume of dissolution medium used to dissolve the dosage form, mL; 0.884 is the percent free base, A_r is the absorbance of the standard preparation, V_2 is the volume of reference standard solution, mL; and C is the capsule claim in mg.

Table 2 shows the plasma level of venlafaxine versus time for one 75 mg conventional Immediate Release (IR) tablet administered every 12 hours, two 75 mg extended release (ER) capsules administered simultaneously every 24 hours, and one 150 mg extended release (ER) capsule administered once every 24 hours in human male subjects. The subjects were already receiving venlafaxine hydrochloride according to the dosage protocol, thus the plasma blood level at zero time when dosages were administered is not zero.

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Table 2
 Plasma venlafaxine level (ng/mL) versus time, conventional tablet (not extended release)
 versus ER capsule

Time (hours)	75 mg (IR)tablet (q 12 h)	2 x 75 mg (ER)capsules (q 24 hr)	1 x 150 mg (ER)capsules (q 24 h)
0	62.3	55.0	55.8
0.5	76.3		
1	135.6	53.3	53.2
2	212.1	69.8	70.9
4	162.0	138.6	133.3
6	114.6	149.0	143.5
8	86.7	129.3	129.5
10		118.4	114.4
12	51.9	105.1	105.8
12.5	74.7		
13	127.5		
14	161.3	90.5	91.3
16	134.6	78.2	78.5
18	106.2		
20	83.6	62.7	63.3
24	57.6	56.0	57.3

5

Table 2 shows that the plasma levels of two 75 mg/capsule venlafaxine hydrochloride ER capsules and one 150 mg/capsule venlafaxine hydrochloride ER capsule provide very similar blood levels. The data also show that the plasma level after 24 hours for either extended release regimen is very similar to that provided by two immediate release 75 mg tablets of venlafaxine hydrochloride administered at 12 hour intervals.

10

Further, the plasma levels of venlafaxine obtained with the extended release formulation do not increase to the peak levels obtained with the conventional immediate release tablets given 12 hours apart. The peak level of venlafaxine from (ER), somewhat below 150 ng/mL, is reached in about six hours, plus or minus two hours, based upon this

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specific dose when administered to patients presently under treatment with venlafaxine hydrochloride (IR). The peak plasma level of venlafaxine, somewhat over 200 ng/ml, following administration of (IR) is reached in two hours and falls rapidly thereafter.

Table 3 shows venlafaxine blood plasma levels in male human subjects having a zero initial blood plasma level. Again, a peak blood plasma concentration of venlafaxine is seen at about 6 hours after dosing with venlafaxine hydrochloride extended release capsules in the quantities indicated. The subjects receiving the single 50 mg immediate release tablet showed a peak plasma level occurring at about 4 hours. For comparative purposes, the plasma levels of venlafaxine for subjects receiving the conventional formulated tablet can be multiplied by a factor of three to approximate the plasma levels expected for a single dose of 150 mg. conventional formulation.

Table 3. Plasma Blood Levels in Human Males Having No Prior Venlafaxine Blood Level

Time (Hours)	1 x 50 mg IR tablet	2 x 75 mg ER capsules	1 x 150 mg ER capsule
0	0	0	0
1	27.87	1.3	0
1.5	44.12	6.0	2.2
2	54.83	20.6	12.8
4	66.38	77.0	81.0
6	49.36	96.5	94.4
8	30.06	93.3	86.9
10	21.84	73.2	72.8
12	15.91	61.3	61.4
14	13.73	52.9	51.9
16	10.67	47.5	41.1
20	5.52	35.2	34.0
24	3.56	29.3	28.5
28	2.53	23.4	22.9
36	1.44	11.9	13.5
48	0.66	5.8	5.2

15

The blood plasma levels of venlafaxine were measured according to the following procedure. Blood samples from the subjects were collected in heparinized evacuated blood

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tubes and the tubes were inverted gently several times. As quickly as possible, the tubes were centrifuged at 2500 rpm for 15 minutes. The plasma was pipetted into plastic tubes and stored at -20°C until analysis could be completed.

To 1 mL of each plasma sample in a plastic tube was added 150 μ L of a stock
5 internal standard solution (150 μ g/mL). Saturated sodium borate (0.2 mL) solution was added to each tube and vortexed. Five mL of ethyl ether was added to each tube which were then capped and shaken for 10 minutes at high speed. The tubes were centrifuged at 3000 rpm for 5 minutes. The aqueous layer was frozen in dry ice and the organic layer transferred to a clean screw cap tube. A 0.3 mL portion of 0.01 N HCl solution was added
10 to each tube and shaken for 10 minutes at high speed. The aqueous layer was frozen and the organic layer removed and discarded. A 50 μ L portion of the mobile phase (23:77 acetonitrile:0.1M monobasic ammonium phosphate buffer, pH 4.4) was added to each tube, vortexed, and 50 μ L samples were injected on a Supelco Supelcoil LC-8-DB, 5 cm x 4.6 mm, 5 μ column in a high pressure liquid chromatography apparatus equipped with a
15 Waters Lambda Max 481 detector or equivalent at 229 nm. Solutions of venlafaxine hydrochloride at various concentrations were used as standards.

Thus, the desired dissolution rate of a sustained release dosage form of venlafaxine hydrochloride, impossible to achieve with hydrogel tablet technology, has been achieved with the film-coated spheroid compositions of this invention.

20

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What is claimed is:

1. An encapsulated, extended release formulation of venlafaxine hydrochloride comprising a hard gelatin capsule containing a therapeutically effective amount of spheroids
5 comprised of venlafaxine hydrochloride, microcrystalline cellulose and hydroxypropyl methylcellulose coated with ethyl cellulose and hydroxypropylmethylcellulose.
2. An extended release formulation according to claim 1 wherein the spheroids are composed of about 37.3% by weight of venlafaxine hydrochloride, about 0.5% by weight
10 of hydroxypropylmethylcellulose 2208, and about 62.17% by weight of microcrystalline cellulose.
3. A composition according to claim 1 wherein the film coating is comprised of ethyl cellulose (4.81% of total weight) and hydroxypropylmethylcellulose (0.85% of total
15 weight).
4. A composition according to claim 1 wherein the film coating is comprised of ethyl cellulose (4.04% of total weight) and hydroxypropylmethylcellulose (0.714% of total weight).
- 20 5. A composition according to claim 1 wherein the film coating is comprised of ethyl cellulose (2.48% of total weight) and hydroxypropylmethylcellulose (0.437% of total weight).
6. A film coating composition which is composed of ethyl cellulose (15% of total weight),
25 having a 44.0-51.0% content of ethoxy groups, and hydroxypropylmethylcellulose (85% of total weight) having a methoxy content of 28.0-30.0% and a hydroxypropoxy group content of 7.0-12.0%.
7. An extended release formulation of venlafaxine hydrochloride for once daily
30 administration which comprises spheroids containing 37.3% venlafaxine, 62.17% microcrystalline cellulose and 0.5% hydroxypropylmethylcellulose type 2208, coated with a quantity of a mixture comprised of 15% ethyl cellulose type HG 2834 and 85% hydroxypropyl-methylcellulose type 2910 sufficient to give coated spheroids having a dissolution profile which gives the desired release rate over a 24 hour period.

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8. An extended release formulation of venlafaxine hydrochloride according to claim 7 which provides lower peak serum levels of up to 150 ng/ml and extended therapeutically effective plasma levels over a twenty four hour period.

5 9. A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active
10 ingredient.

10. A method for eliminating the troughs and peaks of drug concentration in a patients blood plasma attending the therapeutic metabolism of plural daily doses of which comprises administering orally to a patient in need thereof, an encapsulated, extended release
15 formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

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ABSTRACT

EXTENDED RELEASE FORMULATION

5 This invention relates to a 24 hour extended release dosage formulation and unit
dosage form thereof of venlafaxine hydrochloride, an antidepressant, which provides better
control of blood plasma levels than conventional tablet formulations which must be
administered two or more times a day and further provides a lower incidence of nausea and
vomiting than the conventional tablets.

10

EXHIBIT 3

Annals of Clinical Psychiatry, Vol. 9, No. 3, 1997

Once-Daily Venlafaxine Extended Release (XR) and Venlafaxine Immediate Release (IR) in Outpatients with Major Depression

Lynn A. Cunningham, M.D.,¹ for the Venlafaxine XR 208 Study Group

This was a randomized, double-blind, placebo-controlled comparison of the efficacy and safety of once-daily venlafaxine extended release (XR) and venlafaxine immediate release (IR). Outpatients with *DSM-III-R* major depression were randomly assigned to venlafaxine XR, 75 mg once daily, venlafaxine IR, 37.5 mg twice daily, or placebo for a maximum of 12 weeks. If the response was inadequate after 2 weeks of treatment, the dosage of venlafaxine XR or IR could be increased to 150 mg daily. The primary efficacy variables were the 21-item Hamilton Depression (HAM-D) Rating Scale total score and depressed mood item, the Montgomery-Asberg Rating Scale (MADRS) total scores, and the Clinical Global Impressions (CGI) severity scale. Two hundred seventy-eight patients were evaluated for efficacy. Venlafaxine XR was significantly superior ($p < 0.05$) to placebo beginning at week 2 for the HAM-D, week 3 for the MADRS, and week 4 for the CGI severity. Similarly, venlafaxine IR was significantly superior ($p < 0.05$) to placebo beginning at week 2 on the HAM-D total and depressed mood item, week 3 on the MADRS total, and week 6 on the CGI severity scales. Venlafaxine XR exhibited superiority ($p < 0.05$) over venlafaxine IR at week 12 for all efficacy variables. The most common treatment-emergent adverse event with venlafaxine XR was nausea. The incidence of nausea was highest during the first 2 weeks with a low likelihood of developing nausea thereafter. The results of this study indicate that venlafaxine XR is safe, effective, and well tolerated for the treatment of major depression at once-daily doses ranging from 75 to 150 mg.

KEY WORDS: Venlafaxine; major depressive disorder; extended release; clinical trial.

INTRODUCTION

Venlafaxine is a novel antidepressant that selectively inhibits neuronal reuptake of serotonin and norepinephrine, with little activity on dopamine receptors and no monoamine oxidase inhibiting activity (1). Venlafaxine has a low affinity for muscarinic, histaminergic, or adrenergic receptors in the rat brain (1). Venlafaxine has been shown to be effective for the treatment of major depression and significant antidepressant activity has been demonstrated in a broad range of patients (2-10).

Venlafaxine usually is administered at doses from 75 to 225 mg given two or three times daily. With oral administration, venlafaxine is rapidly absorbed, reaches peak plasma levels in approximately 2 h, and undergoes hepatic and renal elimination with an elimination half-life of approximately 5 h for the parent drug and approximately 11 h for the active metabolite, *O*-desmethyl venlafaxine (11). Once-daily venlafaxine extended release (XR) is a microsphere encapsulated formulation that provides a prolonged duration of absorption but the same total extent of absorption of active drug allowing once-daily administration. The potential advantages of a once-daily formulation of venlafaxine are better patient compliance and convenience and improved patient tolerability,

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while maintaining or improving the effectiveness. The purpose of this study was to investigate the efficacy and tolerability of once-daily venlafaxine XR compared with venlafaxine immediate release (IR) and placebo in outpatients with major depression.

METHODS

This was a multicenter, double-blind, placebo-controlled study to compare the efficacy and safety of once-daily venlafaxine XR and venlafaxine IR in outpatients with major depression. The protocol was approved by the appropriate ethics committees at each clinical site, and written informed consent was obtained from patients prior to enrollment.

Patient Selection

Outpatients aged 18 years or older who met *DSM-III-R* criteria for a major depressive episode; had a minimum baseline score of 20 on the 21-item Hamilton Depression Rating Scale (HAM-D)(12), with not more than a 20% decrease in score between screening and baseline; and had symptoms of depression for at least one month before study entry were eligible.

Patients were excluded if they had previously been treated with venlafaxine. Women who were lactating or of childbearing potential with a positive β -human chorionic gonadotropin (HCG) pregnancy test were not included. In addition, patients with a history of clinically significant medical disease or clinically significant abnormalities on a screening physical examination, electrocardiogram (ECG), or laboratory tests; acute suicidal tendencies; a history of a seizure disorder; presence of an organic mental disorder; bipolar disorder; or a history of any psychotic disorder not associated with depression were excluded. Other reasons for exclusion were use of any investigational drug, antipsychotic drug, or electroconvulsive therapy within 30 days, fluoxetine within 21 days, or monoamine oxidase inhibitor, paroxetine, or sertraline within 14 days, or use of any other antidepressant, anxiolytic, sedative-hypnotic drug, or psychotropic drug or substance within 7 days of the start of double-blind treatment; use of any nonpsychotropic drug with psychotropic effects (e.g., β -adrenergic blockers), unless the dosage had been stable for a minimum of one month prior to double-

blind treatment; or a history of drug or alcohol abuse within 1 year of the start of the study.

Study Procedure

Eligible outpatients underwent a prestudy evaluation within 7 ± 3 days before entering the double-blind phase during which single-blind placebo was administered once daily. The prestudy assessments included a complete medical and psychiatric history, a complete physical examination, vital signs, standard clinical laboratory testing and urine drug screen, β -HCG, and a 12-lead ECG. Following the single-blind placebo phase, patients underwent assessment with the HAM-D, the Montgomery-Asberg Depression Rating Scale (MADRS)(13), and the Clinical Global Impressions (CGI) scale (14).

Patients satisfying selection criteria were randomly assigned to either venlafaxine XR, 75 mg once daily in the morning, plus placebo, once daily in the evening, venlafaxine IR, 37.5 mg twice daily in the morning and evening, or placebo, twice daily for 14 days. After day 14, the dosage of venlafaxine XR or IR could be adjusted within the range of 75 to 150 mg/day at the investigators discretion. At the end of the double-blind treatment period, study medications were tapered over a period of up to 2 weeks. All study medications, including placebo, were supplied in matching capsules and were administered with food. Patients were permitted to take chloral hydrate up to 1000 mg at bedtime for sleep, but other psychotropic medications were prohibited.

Study Assessments

Efficacy was assessed throughout the double-blind treatment using the 21-item HAM-D, MADRS, and the CGI scale. The HAM-D was administered at screening, at baseline, and on days 7, 14, 21, 28, 42, 56, and 84. The MADRS and the CGI scale were administered at baseline and on days 7, 14, 28, 42, 56, and 84. The primary efficacy variables were the final on-therapy scores for the 21-item HAM-D, the HAM-D depressed mood item, the MADRS total, and CGI scales. For the HAM-D and MADRS scales, a response was defined as a decrease in total score of at least 50% from baseline; for the CGI scale, a response was defined as a score of 1 (very much improved) or 2 (much improved) on the Global improvement item. A sustained response was defined as improvement that, once observed, persist-

ed until the end of the trial. Patients who withdrew before study completion had efficacy assessments performed within 3 days of the last full dose of study medication. A poststudy evaluation also was administered 4 to 10 days after study medication was discontinued.

Patients were examined and questioned regarding any adverse symptoms. Safety evaluation was based on reports of study events, concomitant medication records, vital signs, weight, ECG, and laboratory tests. A study event was defined as any adverse event experienced by a patient at any time during the study, including treatment-emergent signs or symptoms, a new intercurrent illness, or clinically significant changes in any laboratory test, vital signs, weight, or ECG. Treatment-emergent study events were new adverse events or those that worsened during treatment.

Statistical Analysis

Efficacy analyses were performed on an intent-to-treat basis, which included all patients who were enrolled in the double-blind study, had at least one baseline evaluation on one of the primary efficacy variables, received at least one dose of drug, and had at least one efficacy evaluation while on treatment. A last observation carried forward (LOCF) analysis was used where the last observation for a patient who discontinued was carried forward to all subsequent assessment times. All tests were two-tailed at an α level of 0.05 with a 90% power.

Changes from baseline for HAM-D, MADRS, and CGI scores were assessed using a two-way analysis of covariance (ANCOVA), with treatment and investigator as factors and the baseline score as a covariate. Differences among groups were examined with Fisher's protected LSD multiple comparison procedure. A pairwise comparison was significant if the p values of both the F test and the pairwise comparison were 0.05. The clinical and sustained response rates of the two treatment groups were compared at each time point using Fisher's exact test.

Analysis of variance (ANOVA) was used to test for comparability of treatment groups with respect to age, weight, and baseline scores for the HAM-D total and factors, MADRS total, and CGI severity. The chi-square test or Fisher's exact test was used to compare baseline characteristics, such as sex, concurrent diagnoses, and concomitant medications, and for comparisons among groups in the proportion of

patients discontinuing therapy. The paired t test was used to test for significant within-group changes in mean laboratory values, vital signs, weight, or ECG data over time. Comparisons between groups were made with two-way ANCOVA.

RESULTS

Two hundred ninety-three patients were randomized to study medication and were included in the safety analyses. Data from 15 patients were excluded from the efficacy analyses because no on-treatment assessments were recorded. Baseline demographic and clinical characteristics of the 278 patients included in the intent-to-treat analyses revealed that the groups were comparable (Table 1). A total of 107 (37%) patients withdrew before the end of the study (Table 2). Significantly more patients discontinued venlafaxine XR (11/97; 11%) or venlafaxine IR (12/96; 13%) for adverse effects ($p = 0.015$), while significantly more discontinued placebo (12/100) for unsatisfactory response ($p = 0.01$). Among patients in the venlafaxine IR group, the mean daily dose was 115 to 125 mg per day, and for the venlafaxine XR group it was 124 to 140 mg per day, from day 15 through day 84.

Venlafaxine XR was superior ($p < 0.05$) to placebo at week 2 and from week 4 through week 12 on the HAM-D total, and from week 2 on the HAM-D depressed mood item, week 3 on the MADRS total, and week 4 on the CGI severity scales (Table 3). Venlafaxine IR was superior ($p < 0.05$) to placebo at week 2 and from week 4 through 12 on the HAM-D total and depressed mood item, on the MADRS from week 3 through week 12, and on the CGI severity from week 6 through week 12. Venlafaxine XR was superior ($p < 0.05$) to venlafaxine IR at week 8 on the HAM-D total and CGI severity and at week 12 for all four primary efficacy variables.

Response rates on the HAM-D and MADRS scales were significantly ($p = 0.01$ to $p < 0.001$) higher with venlafaxine XR compared with placebo from week 4 through week 12 (Fig. 1). Response rates on the CGI improvement scale were significantly higher ($p < 0.01$ to $p < 0.001$) with venlafaxine XR from week 3 through week 12. Response rates were superior ($p = 0.05$) with venlafaxine IR compared with placebo on the CGI improvement scale from week 2 through week 12, on the HAM-D scale at weeks 2, 6, and 12, and on the MADRS scale at weeks 8 and 12. Venlafaxine XR was superior ($p < 0.05$) to ven-

Table 1. Baseline Demographics and Clinical Characteristics of the Study Population

Characteristic	Placebo (n = 99)	Venlafaxine XR (n = 92)	Venlafaxine IR (n = 87)
Sex (female:male)	58:41	58:34	58:29
Age (yr) ^a	39.9 ± 10.1	39.7 ± 11.0	42.8 ± 11.4
Age range (yr)	20-65	18-70	19-72
Weight (lb)	173.1 ± 40.9	174.6 ± 42.9	174.0 ± 39.8
Duration of depression (wk)			
0-4	1 (1%)	0	2 (2%)
5-12	7 (7%)	18 (20%)	11 (13%)
13-24	13 (13%)	8 (9%)	12 (14%)
25-48	23 (24%)	20 (22%)	16 (18%)
48-96	27 (27%)	15 (15%)	21 (24%)
>96	28 (28%)	31 (34%)	25 (29%)
Mean HAM-D total	24.9	24.5	24.0
Mean MADRS total	26.6	26.7	26.5
CGI severity of illness			
Mildly ill (3) ^b	4 (4%)	10 (11%)	3 (3%)
Moderately ill (4)	68 (69%)	53 (58%)	72 (83%)
Markedly ill (5)	24 (24%)	28 (30%)	11 (13%)
Severely ill (6)	3 (3%)	1 (1%)	1 (1%)

^aMean ± SD.^bNumber in parentheses refers to the CGI score.

Table 2. Reasons for Premature Withdrawal from the Study

Reason	No. (%) patients			p value ^a
	Placebo (n = 100)	Venlafaxine XR (n = 97)	Venlafaxine IR (n = 96)	
Any reason	41 (41)	28 (29)	38 (40)	0.015
Adverse reaction	2 (2)	11 (11)	12 (13)	
Failed to return	16 (16)	9 (9)	14 (15)	
Patient/subject request	3 (3)	1 (1)	3 (3)	0.01
Unsatisfactory response/efficacy	12 (12)	2 (2)	4 (4)	
Protocol violation	2 (2)	2 (2)	2 (2)	
Other medical/nonmedical event	6 (6)	3 (3)	3 (3)	

^aBetween-group comparisons; Fisher's exact test.

lafaxine IR for HAM-D and MADRS response rates at week 12.

Sustained response rates on the HAM-D total, MADRS total, and CGI improvement scales were significantly higher ($p < 0.05$) with venlafaxine XR and venlafaxine IR than with placebo (Figure 2).

Safety

Adverse study events were the primary reason for premature discontinuation in 2 (2%) placebo-treated, 11 (11%) venlafaxine XR-treated, and 12 (13%) venlafaxine IR-treated patients. Asthenia, diz-

ziness, insomnia, nausea, and nervousness were the most common adverse events causing discontinuation. Treatment-emergent adverse events reported by 3% of patients are shown in Table 4. The most common adverse event was nausea in 43 (45%) venlafaxine IR-treated, 44 (45%) venlafaxine XR-treated, and 10 (10%) placebo-treated patients. The highest incidence of nausea was during the first week with venlafaxine XR (27%) and venlafaxine IR (37%), but the incidence rapidly decreased to only 12% by week 2 in both venlafaxine groups, with further decreases over time. The cumulative probability of developing nausea was lower with venlafaxine XR than with venlafaxine IR.

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Table 3. Adjusted Mean Scores and Between-Group Comparisons for Primary Efficacy Variables from Intent-to-Treat and Last Observation-Carried-Forward Analysis

Week	Placebo (n = 99)	Venlafaxine XR (n = 92)	Venlafaxine IR (n = 87)	p value vs. placebo ^a	
				XR	IR
HAM-D total					
1	20.4	19.8	20.2	0.32	0.78
2	19.3	17.2	17.1	0.02	0.01
3	17.1	15.3	15.9	0.05 ^b	0.20
4	16.0	12.7	13.9	<0.001	0.03
6	15.7	11.4	12.7	<0.001	0.003
8	15.5	10.8	12.9	<0.001	0.01
12	15.8	9.4	12.3	<0.001	0.001
HAM-D Depressed Mood Item					
1	2.32	2.06	2.19	0.02 ^b	0.26
2	2.15	1.82	1.82	0.01	0.01
3	1.84	1.46	1.58	0.005	0.07
4	1.81	1.19	1.39	<0.001	0.003
6	1.76	1.02	1.22	<0.001	<0.001
8	1.75	1.08	1.31	<0.001	0.002
12	1.83	0.84	1.14	<0.001	<0.001
MADRS total					
1	22.8	22.3	21.8	0.59	0.26
2	21.6	20.1	19.5	0.17	0.05†
3	19.9	17.4	17.3	0.02	0.02
4	18.7	14.1	15.5	<0.001	0.01
6	17.8	12.4	13.6	<0.001	<0.001
8	17.9	12.0	13.8	<0.001	<0.001
12	18.3	10.6	13.3	<0.001	<0.001
CGI severity					
1	3.85	3.82	3.90	0.72	0.57
2	3.70	3.49	3.52	0.07	0.15
3	3.44	3.14	3.34	0.03 ^b	0.48
4	3.25	2.75	3.01	0.001	0.13
6	3.13	2.58	2.75	<0.001	0.02
8	3.11	2.36	2.73	<0.001	0.02
12	3.18	2.08	2.67	<0.001	0.002

^aDifference between groups based on comparison of adjusted means.^bComparison not significant because p value of F test not ≤0.05.Table 4. Most Common (≥10% and Twice the Placebo Incidence)^a Treatment-Emergent Adverse Effects Occurring During Double-Blind Treatment with Venlafaxine XR or Venlafaxine IR

	No. (%) of patients with events		
	Placebo (n = 100)	Venlafaxine XR (n = 97)	Venlafaxine IR (n = 96)
Anorexia	4 (4)	10 (10)	6 (6)
Constipation	4 (4)	16 (16)	14 (15)
Diarrhea	6 (6)	13 (13)	5 (5)
Dry mouth	8 (8)	16 (16)	21 (22)
Nausea	10 (10)	44 (45)	43 (45)
Abnormal dreams	0	12 (12)	7 (7)
Dizziness	6 (6)	28 (29)	34 (35)
Somnolence	9 (9)	20 (21)	23 (24)
Sweating	3 (3)	18 (19)	13 (14)
Abnormal ejaculation/orgasm (men)	0/41 (0)	10/37 (27)	2/31 (6)

^aNumber and percentage given are total regardless of treatment relatedness.

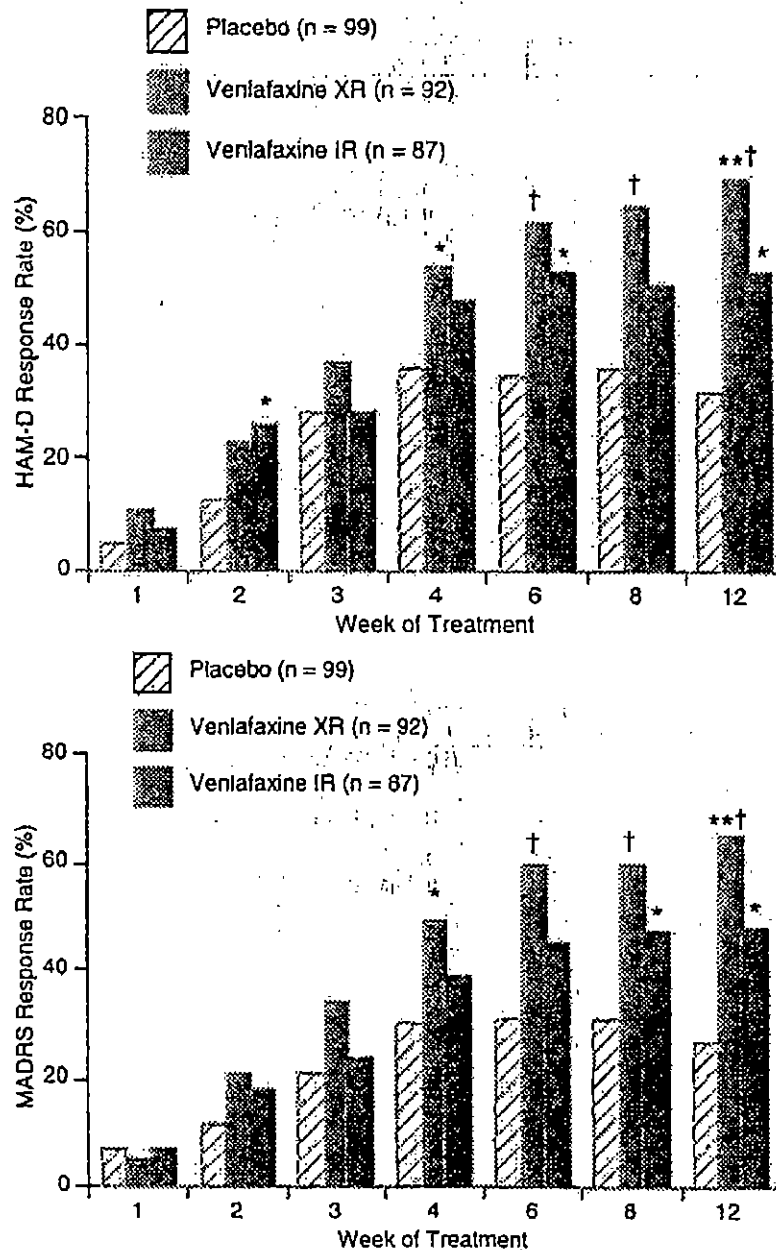


Fig. 1. HAM-D and MADRS response rates for patients treated with placebo, venlafaxine IR, or venlafaxine XR. * $p < 0.05$, $p < 0.001$ vs. placebo; ** $p < 0.05$ for venlafaxine XR vs. venlafaxine IR.

There were no clinically unexpected significant changes from baseline in laboratory values in patients treated with venlafaxine XR or venlafaxine IR compared with placebo-treated patients. Mean changes

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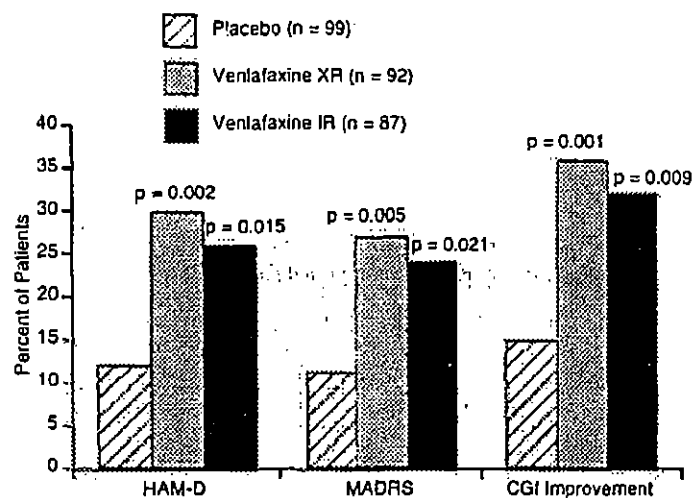


Fig. 2. Sustained response rates on the HAM-D, MADRS, and CGI severity scales for patients treated with placebo, venlafaxine XR, or venlafaxine IR.

from baseline in supine diastolic blood pressure ranged from -0.1 to 2.4 mmHg with venlafaxine XR, -0.3 to 2.6 mmHg with venlafaxine IR, and -2.2 to 0.7 mmHg with placebo. No patients in any treatment group had clinically significant changes in vital signs. No unexpected clinically significant changes attributable to venlafaxine XR or IR occurred in laboratory tests weight or ECG results.

DISCUSSION

We report here the results from a double-blind, placebo-controlled trial of a once-daily formulation of venlafaxine XR for the treatment of major depression. These results show that venlafaxine XR was at least as effective as the venlafaxine IR at most assessment times, with statistical superiority demonstrated at the 12-week assessment. The safety/tolerability profile of venlafaxine XR was comparable to that of venlafaxine IR.

Previously, results from clinical trials with immediate release venlafaxine have demonstrated its effectiveness in the treatment of major depression in a wide range of depressed patients including hospitalized patients and outpatients, the elderly, those with melancholic symptoms, and patients with psychomotor agitation/retardation over a wide range of doses (3-5,7-9,15-17).

This study used a flexible dosage schedule that allowed an increase in the dose to 150 mg daily at

the investigators discretion. The ability to increase the therapeutic response with an increase in dose may offer an advantage. Although 50% or more of patients respond to venlafaxine at doses of 75 mg/day (5,10), studies with venlafaxine have shown an increased therapeutic response with an increased dose (5-7).

While older antidepressants such as the tricyclic antidepressants are effective in many patients, their use is often limited by intolerable side effects, and patients are exposed to potentially serious cardiac toxicity (18,19). Even the newer selective serotonin reuptake inhibitors (SSRIs) may be associated with agitation, insomnia, and sexual dysfunction (20). In addition, SSRIs may be limited by clinically significant drug-drug interactions (21). The results from this trial demonstrated an acceptable tolerability profile with both formulations of venlafaxine. Nausea was the most common adverse event with venlafaxine, but as reported previously (5), the incidence decreased rapidly after the first 1 to 2 weeks of use. In fact, there were virtually no additional reports of nausea with venlafaxine XR beyond day 24 of therapy. The potential for elevated blood pressure at doses above 200 mg/day has been noted previously with venlafaxine (22). Results from this study showed no difference between either venlafaxine group and placebo with respect to clinically significant changes in blood pressure or heart rate.

In summary, the results from this double-blind, placebo-controlled comparative study indicate that

once-daily venlafaxine XR was significantly more effective at weeks 8 and 12 and exhibited better tolerability compared with venlafaxine IR given twice daily for treating major depression. The majority of patients respond to a dose of 75 mg given once daily, but venlafaxine XR offers the flexibility of an improved response with a dosage increase. Thus, once-daily venlafaxine XR should enhance patient compliance while potentially improving on the efficacy and tolerability of the standard venlafaxine formulation for treating patients with major depression.

ACKNOWLEDGMENTS

This study was supported by Wyeth-Ayerst Research, Radnor, Pennsylvania. Members of the Venlafaxine XR 208 Study Group are as follows: Barry Baumel, M.D., Neuromedical Research Associates, Miami Beach, FL; Lynn A. Cunningham, M.D., Vine Street Clinical Research Center, Springfield, IL; Bruce I. Diamond, Ph.D., Clinical Therapeutics Section, Biotech Park, Augusta, GA; Arthur M. Freeman, III, M.D., Department of Psychiatry, Louisiana State University, Shreveport, LA; Robert W. Gibson, Jr., M.D., Piedmont Research Associates, Winston-Salem, NC; Barbara L. Kennedy, M.D., Ph.D., Department of Psychiatry, University of Louisville, Louisville, KY; Arifulla Khan, M.D., Department of Psychiatry and Behavioral Sciences, University of Washington, Seattle, WA; Roger O. Patrick, Ph.D., Bellevue Family Medicine, Englewood, CO; Robert A. Riesenberger, M.D., BioBehavioral Research Center, Decatur, GA; Ram K. Shrivastava, M.D., Eastside Comprehensive Medical Services, New York, NY; Stephen M. Stahl, M.D., Ph.D., Clinical Neuroscience Research Center, San Diego, CA; Kenneth I. Weiss, M.D., Delaware Valley Research Associates, Inc., King of Prussia, PA.

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EXHIBIT 4

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

WYETH,	:	Civil No. 03-1293 (KSH)
	:	
Plaintiff,	:	
	:	
v.	:	
	:	
TEVA PHARMS., USA, et al.,	:	ORDER
	:	
Defendants.	:	

This matter having come before the Court by way of letters dated February 22, 2005, March 1, 2005, March 7, 2005, March 10, 2005, March 11, 2005, and March 14, 2005¹ in which defendants Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceuticals, Ltd. ("Teva Ltd.") (hereinafter collectively referred to as "Teva")² seek leave to amend their Answers to add the affirmative defense of unenforceability based upon "inequitable conduct"³; and the

¹The Court reviewed the letters of counsel dated March 10, 11, and 14, 2005 dealing with the ruling in Cephalon v. Mylan, 03-1294 (March 8, 2005) (JCL) in which Judge Falk granted Teva leave to amend its Answer. In Cephalon, Judge Falk noted "the primary argument in opposition to amendment [was] one of futility" (Transcript of Oral Argument dated February 22, 2005 at 6:15-17.) Unlike Cephalon, the issue here is primarily whether or not "good cause" under Rule 16 exists to adjust the Court's Pretrial Scheduling Order. Given the distinction between the Rule 16 analysis applicable here, and the Rule 15 futility analysis employed in Cephalon, the Court finds the Cephalon decision does not apply to the present application.

²Teva USA and Teva Ltd. make their application jointly and their proposed amended affirmative defenses rely upon the same factual and legal bases. (Compare Letter from Michael E. Patunas dated February 22, 2005, Exh. A at ¶¶ 68-91 with Exh. B at ¶¶ 65-88.)

³Teva's proposed unenforceability affirmative defense alleges Wyeth made misrepresentations to the United States Patent and Trademark Office ("PTO") in that it (1) overstated the difference in water solubility between its drug venlafaxine hydrochloride and Teva's propranolol hydrochloride (Teva Ltd. Amended Answer at ¶¶ 69-77; Teva USA Amended Answer at ¶¶ 66-74); and (2) stated that venlafaxine extended release formulation had a statistically significant improvement in incidence of nausea and vomiting over conventional venlafaxine hydrochloride, which it allegedly knew was unsupported at that time (Teva Ltd.

Court having reviewed all submissions of the parties;

and Teva arguing that relief from the Pretrial Scheduling Order and permission to file a motion for leave to file Amended Answers should be granted because: (1) the facts upon which it relies in support of its proposed amended affirmative defense "came to light during the depositions of Richard Mangano and Richard Rudolph taken, respectively, on February 4 and 8, 2005" (Letter from Michael E. Patunas dated February 22, 2005 at 1), (2) it has diligently pursued discovery and should not be penalized because it discovered critical facts late in the discovery process (id. at 2), and (3) "Wyeth has been on notice since August 2003 of Teva's efforts to develop an inequitable conduct defense and counterclaim" and its theory has not changed (id. at 2-3);

and Wyeth arguing that Teva's application should be denied with respect to its first theory

Amended Answer at ¶¶ 78-91; Teva USA Amended Answer at ¶¶ 75-88). Teva alleges these misrepresentations amount to "inequitable conduct" and render the patent unenforceable.

In support of its first claim of inequitable conduct, Teva relies upon a June 3, 1993 internal correspondence entitled "EFFEXOR SR" [Wyeth 019-020221] (Teva Ltd. Amended Answer at ¶ 69; Teva USA Amended Answer at ¶ 66); representations made in U.S. Patent 4,138,475 ("the McAnish patent") (Teva Ltd. Amended Answer at ¶¶ 70-71; Teva USA Amended Answer at ¶¶ 67-68); an April 13, 1999 correspondence from Wyeth to the PTO (Teva Ltd. Amended Answer at ¶ 72; Teva USA Amended Answer at ¶ 69); statements within Wyeth's May 16, 1996 New Drug Application ("NDA") (Teva Ltd. Amended Answer at ¶¶ 74-75; Teva USA Amended Answer at ¶¶ 71-72). Teva does not rely upon facts discovered during the February, 2005 depositions in support of its first theory of inequitable conduct.

In support of its second claim of inequitable conduct, Teva relies upon independent claims asserted within the United States Patent Numbers 6,274,171 B1 ("the '171 patent") and 6,403,120 B1 ("the '120 patent") (Teva Ltd. Amended Answer at ¶¶ 78-83; Teva USA Amended Answer at ¶¶ 75-80) and the deposition transcripts of Richard Mangano and Richard Rudolph (Teva Ltd. Amended Answer at ¶¶ 85-88; Teva USA Amended Answer at ¶¶ 82-85), which were taken on February 4 and 8, 2005, respectively (Letter from Michael E. Patunas dated February 22, 2005 at 1).

of inequitable conduct because it has been aware of the facts it now alleges support its inequitable conduct affirmative defense for months (Letter from Kevin J. McKenna dated March 1, 2005 at 2-6);

and Wyeth further arguing that, with respect to the second theory of inequitable conduct, Teva has had access to the materials upon which it relies since October, 2003 and has not explained why the recent deposition testimony clarified information that Teva has had in its possession since October, 2003, (*id.* at 7);

and Wyeth further arguing that Teva's application should be denied with respect to both theories of inequitable conduct because it has presented no evidence that anyone involved in the prosecution of the patents in suit acted with an intent to deceive (*id.* at 6-7);

and Federal Rule of Civil Procedure 16 providing that a court shall enter scheduling orders to allow for "judicial control over a case and to schedule dates for completion by the parties of the principal pretrial steps." Harrison Beverage Co. v. Dribeck Importers, Inc., 133 F.R.D. 463, 469 (D.N.J. 1990) (quotations omitted); see also Newton v. A.C. & S., Inc., 918 F.2d 1121, 1126 (3d Cir. 1990) (stating the purpose of Rule 16 is to provide for judicial control over a case, streamline proceedings, maximize the efficiency of the court system, and actively manage the timetable of case preparation to expedite the speedy and efficient disposition of cases);

and the Court having entered a Pretrial Scheduling Order in this case pursuant to Rule 16 on June 30, 2003 that set the deadline for filing motions to amend as December 31, 2003;

and it appearing that modification of scheduling orders is discretionary, Harrison Beverage Co., 133 F.R.D. at 469;

and Rule 16 further providing that the party seeking modification of a pretrial scheduling

order must show "good cause" for a court to change the Order, Fed. R. Civ. P. 16(b), and that a court may modify a Rule 16 scheduling order upon "a showing of good cause if it cannot reasonably be met despite the diligence of the party seeking the extension." Fed. R. Civ. P. 16, Advisory Committee's Note, on Subdivision (b);

and it further appearing that allowing extensions in the absence of "good cause" would "deprive trial judges of the ability to effectively manage the cases on their overcrowded dockets" and severely impair the utility of scheduling orders. Koplove v. Ford Motor Co., 795 F.2d 15, 18 (3d Cir. 1986);

and it further appearing, in the context of a motion to amend, that "[t]o argue that there should be a liberal policy of freely permitting amendments is to ignore . . . the purposes of case management and the scheduling orders which are at the heart of case management," Harrison Beverage Co., 133 F.R.D. at 469 (quoting Koplove, 795 F.2d at 18), and that the Court is left with the question of whether or not defendants could not have reasonably been expected to meet the December 31, 2003 deadline despite their diligence;

and no applications having been made to adjust the deadline to amend pleadings before the February 17, 2005 telephone conference;

and the Court noting that the application to file a motion for leave to file Amended Answers was not raised until the close of fact discovery;

and it appearing that, with respect to its first theory of inequitable conduct, Teva has not shown that the information that Wyeth overstated the difference in water solubility between its drug venlafaxine hydrochloride and Teva's propranolol hydrochloride (Teva Ltd. Amended Answer at ¶¶ 69-77; Teva USA Amended Answer at ¶¶ 66-74) was inaccessible to it such that it

could not, through due diligence, have been discovered within the deadlines set forth in the June 30, 2003 Pretrial Scheduling Order or that they could not have sought leave to extend the deadline to amend pleadings long before the close of fact discovery;

and it further appearing, with respect to its second theory of equitable conduct, Teva had access to all of the information regarding Wyeth's statements to the PTO relating to incidence of nausea and vomiting in venlafaxine extended release formulation as compared to conventional venlafaxine hydrochloride (Teva Ltd. Amended Answer at ¶¶ 78-91; Teva USA Amended Answer at ¶¶ 75-88), except for the deposition testimony of Messrs. Mangano and Rudolph;

and it further appearing that Teva has not explained how these depositions clarified information regarding Wyeth's representations to the PTO about the incidence of nausea and vomiting;

and while the Court will grant Teva's request to file a motion for leave to file an Amended Answer regarding Wyeth's representations to the PTO about incidence of nausea and vomiting, Teva shall include an explanation of how the February, 2005 depositions provided newly discovered evidence that it did not possess before the February 17, 2005 telephone conference;

and the parties being advised that if good cause is not presented, then the Court may consider whether or not Fed. R. Civ. P. 16 should bar the motion;

and the parties being advised that nothing herein is to be construed as a ruling regarding whether or not considerations under Fed. R. Civ. P. 15 should bar an amendment at this time;

and for good cause shown,

IT IS on this 22nd day of March, 2005

ORDERED that Teva's application for leave to adjust the Pretrial Scheduling Order pursuant to Rule 16 and to file a motion for leave to file Amended Answers to add the affirmative defense of unenforceability on the basis of the alleged "inequitable conduct" is granted only insofar as it seeks to allege that Wyeth misrepresented information related to incidence of nausea and vomiting in venlafaxine extended release formulation as compared to conventional venlafaxine hydrochloride (Teva Ltd. Amended Answer at ¶¶ 78-91; Teva USA Amended Answer at ¶¶ 75-88);

IT IS FURTHER ORDERED that Teva's application for leave to adjust the Pretrial Scheduling Order pursuant to Rule 16 and to file a motion to amend its Answers to add the affirmative defense of unenforceability on the basis of the alleged "inequitable conduct" that Wyeth overstated the difference in water solubility between its drug venlafaxine hydrochloride and Teva's propranolol hydrochloride (Teva Ltd. Amended Answer at ¶¶ 69-77; Teva USA Amended Answer at ¶¶ 66-74) is denied;

IT IS FURTHER ORDERED that Teva's motion for leave to file Amended Answers shall be filed no later than **April 1, 2005**. Any responsive papers shall be filed no later than **April 11, 2005**. There shall be no reply unless requested by the Court;

IT IS FURTHER ORDERED that all of the terms of the Orders dated August 9, 2004, December 21, 2004, February 20, 2005, and March 14, 2005 shall remain in full force and effect.

s/ Patty Shwartz
United States Magistrate Judge

EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH,

Plaintiff,

v.

IMPAX LABORATORIES, INC.,

Defendant.

Civil Action No.: 06-222 JJF

DEFENDANT'S IMPAX LABORATORIES, INC.'S

FIRST SET OF REQUESTS FOR PRODUCTION (NOS. 1-3)

Pursuant to Federal Rule of Civil Procedure 34, Defendant IMPAX Laboratories, Inc. ("IMPAX" or "Defendant"), by its counsel, directs the following Requests for Production to Plaintiff Wyeth ("WYETH" or "Plaintiff") to produce all documents and things requested herein at the offices of Heller Ehrman LLP, 333 Bush Street, San Francisco, California, 94104, within 33 days of the date of service hereof.

When used in the following requests for production, the following definitions apply:

1. "WYETH" means Plaintiff Wyeth and that company as it was previously named and any related companies, divisions, or subsidiaries, past or present, and the past or present directors, officers, employees, agents, or attorneys thereof, including but not limited to foreign subsidiaries and divisions.

2. "AND/OR": As used herein, the conjunctions "and" and "or" shall be interpreted conjunctively and shall not be interpreted to exclude any information otherwise within the scope of the request.

3. DATE means the exact day, month, AND year, if so ascertainable, OR if not, the best approximation (including relationship to other events).

4. "DOCUMENT" or "DOCUMENTS" means all written, printed, typed, electronically produced, electronically stored, photostatic, photographed, recorded, OR otherwise reproduced communications OR records of every kind AND description, whether comprised of letters, words, pictures, sounds, symbols, OR combinations thereof. DOCUMENTS include originals as well as drafts, copies, marked-up copies, non-identical duplicates, AND computer files, including backup OR archival copies. DOCUMENTS include DOCUMENTS created AND/OR received by WYETH AND/OR by any of WYETH'S consultants, agents, AND/OR any other PERSON OR PERSONS.

5. "PERSON" refers to any natural person, firm, association, organization, partnership, business, trust, corporation, OR public entity.

6. "IDENTIFY" used with respect to a DOCUMENT means to provide: the kind of DOCUMENT (e.g., letter, memo, etc.); the title OR name by which the DOCUMENT is referred to; the DATE of the DOCUMENT; the identity of its author OR the PERSON creating the DOCUMENT; the identity of each PERSON to whom the DOCUMENT was addressed, sent, OR copied; the present location of the original AND all copies thereof; the name of the custodian of the DOCUMENT; AND a general description of the subject matter.

7. "IDENTIFY" used with respect to a PERSON, means to state:

(a) His, her, OR its full name AND all known business OR other addresses AND telephone numbers;

(b) If a natural PERSON, his or her last known residence address AND telephone number; AND

(c) Such PERSON'S relationship to YOU.

8. "IDENTIFY" used in reference to an act, instance, transaction, occasion, oral discussion, conversation, COMMUNICATION, OR event, means to state the DATE

upon which AND the location at which it occurred, the identity of each PERSON who participated therein OR who was present when it occurred, its substance (*i.e.* what was said AND by whom AND/OR what transpired) AND the identity of each DOCUMENT, which, in whole OR in part, was the subject of the act OR in which it is manifested, referred to OR expressed.

INSTRUCTIONS

1. Each request below extends to any DOCUMENTS and things in the possession, custody OR control of WYETH. The DOCUMENT is deemed to be in WYETH'S possession, custody OR control, if it is in WYETH'S physical custody, OR if it is in the physical custody of any other PERSON and WYETH (a) owns such DOCUMENTS in whole OR in part; (b) has a right by contract, statute OR otherwise to use, inspect, examine OR copy such DOCUMENTS on any terms; (c) has an understanding, express OR implied, that WYETH may use, inspect, examine OR copy such DOCUMENTS on any terms; OR (d) has, as a practical matter, been able to use, inspect, examine OR copy such DOCUMENTS when WYETH has sought to do so. Such DOCUMENTS shall include, without limitation, DOCUMENTS that are in the custody of WYETH'S attorneys OR other agents.

2. Unless otherwise stated, the time period covered by this notice is up to AND including the DATE on which the DOCUMENTS are produced.

3. Pursuant to rule 26(e) of the Federal Rules of Civil Procedure, these requests for production of DOCUMENTS and things are deemed continuing to the fullest extent permissible AND to apply to all DOCUMENTS that WYETH subsequently creates, develops, discovers OR receives.

4. If WYETH cannot respond to any request in full, it should respond to the fullest extent possible, explain why it cannot respond to the remainder, AND describe the nature of the DOCUMENTS that it cannot furnish.

5. It is not intended that this notice require the disclosure of any DOCUMENTS that are privileged. For any DOCUMENTS and things withheld on such grounds, OR any other grounds, please provide a written response with the following information:

- (a) A description of the DOCUMENT sufficiently particular to IDENTIFY it for purposes of a court order;
- (b) The DATE of the DOCUMENT;
- (c) The nature of the protection claimed;
- (d) A list of all PERSONS who participated in the preparation of the DOCUMENT;
- (e) A list of all PERSONS who have received OR reviewed copies of the DOCUMENT; AND
- (f) A list of all PERSONS to whom the DOCUMENT was circulated, OR its contents communicated.

REQUESTS FOR PRODUCTION

REQUEST NO. 1:

All DOCUMENTS and things produced and in discovery by WYETH in *Wyeth v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.*, Civil Action No. 03-CV-1293 (WJM) before the United States District Court for the District of New Jersey.

REQUEST NO. 2:

All DOCUMENTS related to requests for production propounded by Teva Pharmaceutical Industries Ltd. in *Wyeth v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.*, Civil Action No. 03-CV-1293 (WJM) before the United States District Court for the District of New Jersey, including but not limited to requests for production, responses and objections to requests for production, meet and confer

letters regarding requests for production, and other correspondence regarding requests for production.

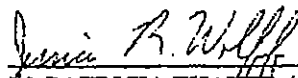
REQUEST NO. 3:

All transcripts of hearings AND depositions conducted in connection with *Wyeth v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.*, Civil Action No. 03-CV-1293 (WJM) before the United States District Court for the District of New Jersey, with those portions of the transcripts redacted that were designated as confidential by Defendant Teva Pharmaceuticals USA, Inc. AND/OR Teva Pharmaceutical Industries Ltd.

REQUEST NO. 4:

All DOCUMENTS, including but not limited to exhibits, presentations, and demonstratives, introduced or used at hearings AND depositions conducted in connection with *Wyeth v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.*, Civil Action No. 03-CV-1293 (WJM) before the United States District Court for the District of New Jersey, with those portions of the DOCUMENTS redacted that were designated as confidential by Defendant Teva Pharmaceuticals USA, Inc. AND/OR Teva Pharmaceutical Industries Ltd.

Dated: June 23, 2006


M. PATRICIA THAYER (pro hac vice)
JOHN M. BENASSI (pro hac vice)
JESSICA R. WOLFF (pro hac vice)
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MARY B. MATTERER (I.D. No. 2696)
MORRIS JAMES HITCHENS & WILLIAMS LLP
222 Delaware Ave., 10th Floor
Wilmington, DE 19801
Telephone: (302) 888-6800

Attorneys for Defendant IMPAX LABORATORIES, INC.

SF 1273887 v2

CERTIFICATE OF SERVICE

I, Francesca Romero, declare:

I am over 18 years of age and a party to this action. I am a resident of the County of San Diego, State of California. My business address is: 4350 La Jolla Village Drive, San Diego, California 92122.

On June 23, 2006, I served the following document:

**DEFENDANT'S IMPAX LABORATORIES, INC.'S FIRST SET OF
REQUESTS FOR PRODUCTION (NOS. 1-3)**

upon counsel of record listed below by email transmission and U.S. Mail:

Jack B. Blumenfeld
Melissa S. Myers
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1201 North Market Street
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Wilmington, DE 19899-1347
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Attorneys for Plaintiff
WYETH

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Garrett & Dunner L.L.P.
901 New York Avenue, N.W.
Washington, DC 20001
Tel: (202) 408-4000
Fax: (202) 408-4400

Attorneys for Plaintiff
WYETH

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed this 23rd day of June, 2006, at San Diego, California.

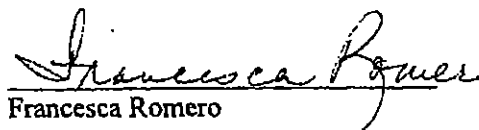

Francesca Romero

EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH,)	
)	
)	
Plaintiff,)	
)	Civil Action No.: 06-222 JJF
v.)	
)	
IMPAX LABORATORIES, INC.,)	
)	
Defendant.)	
_____)	

DEFENDANT IMPAX LABORATORIES, INC.'S

SECOND SET OF REQUESTS FOR PRODUCTION (NOS. 5-86)

Pursuant to Federal Rule of Civil Procedure 34, Defendant Impax Laboratories, Inc. by its counsel, directs the following Requests for Production to Plaintiff Wyeth to produce all documents and things requested herein at the offices of Heller Ehrman LLP, 333 Bush Street, San Francisco, California, 94104, within 30 days of the date of service hereof.

DEFINITIONS

When used in the following requests for production, the following definitions apply:

1. "WYETH" or "PLAINTIFF" means Plaintiff Wyeth and that company as it was previously named and any related companies, parents, divisions, or subsidiaries, past or present, located in the U.S. or abroad, and the past or present directors, officers, employees, agents, representatives or attorneys thereof.
2. "IMPAX" or "DEFENDANT" means Defendant IMPAX Laboratories, Inc. and its past or present directors, officers, employees, agents, representatives or attorneys known to WYETH.

3. "CONCERNING" means referring to, relating to, regarding, reflecting, associated with, comprising, constituting, containing, demonstrating, describing, discussing, evidencing, evincing, indicating, on the subject of, on the topic of, showing, or prepared in connection with the stated matter.

4. "DATE" means the exact day, month, and year, if so ascertainable, or if not, the best approximation (including relationship to other events).

5. "DOCUMENT" or "DOCUMENTS" means all written, printed, typed, electronically produced, electronically stored, photostatic, photographed, recorded, or otherwise reproduced communications or records of every kind and description, whether comprised of letters, words, pictures, sounds, symbols, or combinations thereof. DOCUMENTS include originals as well as drafts, copies, marked-up copies, non-identical duplicates, and computer files, including backup or archival copies.

6. "THING" or "THINGS" means any tangible item, including without limitation models, prototypes, research models or samples, and samples of any device or apparatus, or product.

7. "PERSON" means any natural person, firm, association, organization, partnership, business, trust, corporation, or public entity.

8. "IDENTIFY" used with respect to a DOCUMENT means to provide: the kind of DOCUMENT (e.g., letter, memo, etc.); the title or name by which the DOCUMENT is referred to; the DATE of the DOCUMENT; the identity of its author or the PERSON creating the DOCUMENT; the identity of each PERSON to whom the DOCUMENT was addressed, sent, or copied; the present location of the original and all copies thereof; the name of the custodian of the DOCUMENT; and a general description of the subject matter.

9. "IDENTIFY" used with respect to a PERSON, means to state:

(a) His, her, or its full name and all known business or other addresses and telephone numbers;

(b) If a natural PERSON, his or her last known residence address and telephone number; and

(c) Such PERSON's relationship to WYETH.

10. "IDENTIFY" used in reference to an act, instance, transaction, occasion, oral discussion, conversation, communication, or event, means to state the DATE upon which and the location at which it occurred, the identity of each PERSON who participated therein or who was present when it occurred, its substance (i.e. what was said and by whom and/or what transpired) and the identity of each DOCUMENT, which, in whole or in part, was the subject of the act or in which it is manifested, referred to or expressed.

11. "PTO" means the United States Patent and Trademark Office.

12. "FDA" means the United States Food and Drug Administration.

13. "NDA" means New Drug Application.

14. "ANDA" means Abbreviated New Drug Application.

15. "INDA" means Investigational New Drug Application.

16. "ORANGE BOOK" means the FDA publication entitled, *Approved Drug Products with Therapeutic Equivalence Evaluations*.

17. "IMPAX'S VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE CAPSULE" means those pharmaceutical products that are the subject of ANDA No. 78-057.

18. "VENLAFAXINE" means the compound 1-[(2-dimethylamino)-1-(4-methoxyphenyl) ethyl] cyclohexanol commonly known as venlafaxine, as well as all compositions, formulations, and preparations containing venlafaxine, including without limitation VENLAFAXINE and other pharmaceutically acceptable salts of venlafaxine.

19. "EFFEXOR" means the VENLAFAXINE product sold by WYETH as Effexor®.

20. "EFFEXOR XR" means the VENLAFAXINE product sold by WYETH as Effexor® XR.

21. "PATENTS IN SUIT" means U.S. Patent No. 6,274,171 B1, U.S. Patent No. 6,403,120 B1, U.S. Patent No. 6,419,958 B2, and any other patent asserted by WYETH as infringed by IMPAX in the above-captioned action, individually or collectively.

22. "NAMED INVENTORS" means Deborah M. Sherman, John C. Clark, John U. Lamer, Steven A. White, and any other person listed as an inventor for the PATENTS IN SUIT, individually or collectively.

23. For the purposed of these requests for production only, "EXTENDED RELEASE FORMULATION" means a formulation which releases the active ingredient at a slower rate than the immediate release formulation of the active ingredient such that the desired dosing frequency is or would be less than that for the immediate release formulation.

INSTRUCTIONS

A. Each request below extends to any DOCUMENTS and THINGS in the possession, custody or control of WYETH. A DOCUMENT or THING is deemed to be in your possession, custody or control, if it is in your physical custody, or if it is in the physical custody of any other PERSON and you (a) own such DOCUMENTS in whole or in part; (b) have a right by contract, statute or otherwise to use, inspect, examine or copy such DOCUMENTS on any terms; (c) have an understanding, express or implied, that you may use, inspect, examine or copy such DOCUMENTS on any terms; or (d) have, as a practical matter, been able to use, inspect, examine or copy such DOCUMENTS when you have sought to do so. Such DOCUMENTS or THINGS shall include, without limitation, DOCUMENTS that are in the custody of your attorneys or other agents.

B. In construing these requests, the plural shall include the singular and the singular shall include the plural; a masculine, feminine, or neuter term shall include all

other genders; the terms "or," "and," "and/or," and "including" shall be construed conjunctively and inclusively rather than exclusively so as to bring within the scope of the request that which otherwise might be construed as being outside the scope of said request; and the terms "all" and "any" shall be interpreted inclusively so as to mean both "all" and "any" whenever either term is used.

C. Unless otherwise stated, the time period covered by this notice is up to and including the DATE on which the DOCUMENTS are produced.

D. Pursuant to Federal Rule of Civil Procedure 26(e), these requests for production of DOCUMENTS and THINGS are deemed continuing to the fullest extent permissible and to apply to all DOCUMENTS and THINGS that you subsequently create, develop, discover, or receive.

E. If you cannot respond to any request in full, you should respond to the fullest extent possible, explain why you cannot respond to the remainder, and describe the nature of the DOCUMENTS or THINGS that you cannot furnish.

F. Pursuant to Federal Rule of Civil Procedure 26(b)(5), it is not intended that this notice require the disclosure of any DOCUMENTS or THINGS that are privileged where such privilege has not been waived. For any DOCUMENTS and THINGS withheld on such grounds, or any other grounds, please provide a written response with the following information:

(i) A description of the DOCUMENT or THING with sufficient particularity to IDENTIFY it for purposes of a court order, including without limitation control numbers or Bates label numbers;

(ii) The DATE stated on the DOCUMENT or THINGS, or alternatively, the DATE it was created or first came into existence;

(iii) The nature of the protection claimed;

(iv) A list of all PERSONS who participated in the preparation of the DOCUMENT or THING;

(v) A list of all PERSONS who have received or reviewed copies of the DOCUMENT or THING; and

(vi) A list of all PERSONS to whom the DOCUMENT or THING was circulated, or its contents (if applicable) communicated.

G. Pursuant to Federal Rule of Civil Procedure 34, responsive DOCUMENTS and THINGS shall be produced as kept by its custodian in the ordinary course of business or shall be produced in a manner organized and labeled to correspond with the categories in these requests.

E. Pursuant to Federal Rule of Civil Procedure 34, in responding to these requests, you must make a diligent search of your records and of other papers or materials in your possession or available to you or your representatives. If, after exercising due diligence, you are unable to determine the existence of any DOCUMENTS or THINGS falling within a request, you shall so state in written responses.

F. If a refusal to provide DOCUMENTS or THINGS responsive to any request is asserted on the grounds of burdensomeness, you should state in detail the reason(s) for your objection(s), including the number and nature of documents or records needed to be searched and/or produced, the location of the documents, the custodian of the documents, and the number of person hours and costs required to conduct the search.

G. If any request is unclear or ambiguous to you, you are requested to contact undersigned counsel as soon as possible so that the request can be clarified to avoid unnecessary delays in discovery.

REQUESTS FOR PRODUCTION

REQUEST NO. 5:

All DOCUMENTS and THINGS that were relied upon in responding to, or are identified in, WYETH's responses to Defendant Impax Laboratories, Inc.'s First Set of Interrogatories, served herewith.

REQUEST NO. 6:

All DOCUMENTS and THINGS identified in Plaintiff's Initial Disclosure Statement Pursuant to Fed. R. Civ. P. 26(a)(1), dated June 23, 2006, and any supplements or amendments thereto.

REQUEST NO. 7:

All DOCUMENTS and THINGS in the possession of Deborah M. Sherman CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

REQUEST NO. 8:

All DOCUMENTS and THINGS in the possession of John C. Clark CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

REQUEST NO. 9:

All DOCUMENTS and THINGS in the possession of John U. Lamer CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

REQUEST NO. 10:

All DOCUMENTS and THINGS in the possession of Stephen A. White CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

REQUEST NO. 11:

All DOCUMENTS and THINGS in the possession of Rebecca R. Barrett
CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and
clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

REQUEST NO. 12:

All DOCUMENTS and THINGS in the possession of Egon E. Berg CONCERNING the
PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and clinical studies
600B-208-US, 600B-209-US, and 600B-367-EU.

REQUEST NO. 13:

All DOCUMENTS and THINGS in the possession of Steven R. Eck CONCERNING the
PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and clinical studies
600B-208-US, 600B-209-US, and 600B-367-EU.

REQUEST NO. 14:

All DOCUMENTS and THINGS in the possession of Eliseo Salinas
CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and
clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

REQUEST NO. 15:

All DOCUMENTS and THINGS in the possession of Joseph M. Mahady
CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and
clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

REQUEST NO. 16:

All DOCUMENTS and THINGS in the possession of Robin P. Enever
CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and
clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

REQUEST NO. 17:

All DOCUMENTS and THINGS in the possession of Richard Deneale
CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and
clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

REQUEST NO. 18:

All DOCUMENTS and THINGS in the possession of Dr. Mangano
CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and
clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

REQUEST NO. 19:

All DOCUMENTS and THINGS in the possession of Dr. Alaburda
CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and
clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

REQUEST NO. 20:

All DOCUMENTS and THINGS in the possession of Richard Rudolph
CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and
clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

REQUEST NO. 21:

All DOCUMENTS and THINGS in the possession of Wilfredo Ortega-Leone CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

REQUEST NO. 22:

All DOCUMENTS and THINGS CONCERNING any claimed infringement of the PATENTS IN SUIT by IMPAX.

REQUEST NO. 23:

All DOCUMENTS and THINGS CONCERNING any claim by WYETH that IMPAX's alleged infringement was willful or that this is an exceptional case.

REQUEST NO. 24:

All intrinsic or extrinsic evidence on which WYETH intends to rely in construing the claims of the PATENTS IN SUIT.

REQUEST NO. 25:

All DOCUMENTS and THINGS that contradict or refute WYETH's construction or interpretation of the claims, claim elements, claim terms, or claim phrases of the PATENTS IN SUIT.

REQUEST NO. 26:

All DOCUMENTS and THINGS CONCERNING IMPAX'S VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE CAPSULE.

REQUEST NO. 27:

All DOCUMENTS and THINGS CONCERNING any claimed infringement of the PATENTS IN SUIT by any PERSON other than IMPAX, including without limitation notice to the other PERSON, and responses by the other PERSON CONCERNING the PATENTS IN SUIT.

REQUEST NO. 28:

All DOCUMENTS and THINGS CONCERNING any litigation or other contested proceedings involving the PATENTS IN SUIT.

REQUEST NO. 29:

All pleadings and correspondence served by and between the parties in *Wyeth v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.*, Civil Action No. 03-CV-1293 (WJM) before the United States District Court for the District of New Jersey, including without limitation complaints, answers, replies to counterclaims, discovery requests and responses thereto, discovery dispute briefing and exhibits, motions, claim construction briefing and exhibits, and meet and confer letters regarding disputes between the parties.

REQUEST NO. 30:

All DOCUMENTS and THINGS CONCERNING settlement of disputes regarding the infringement of, or licensing of, the PATENTS IN SUIT, including without limitation the settlement agreement between the parties in *Wyeth v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.*, Civil Action No. 03-CV-1293 (WJM) before the United States District Court for the District of New Jersey, and negotiations regarding that dispute or disputes with other PERSON.

REQUEST NO. 31:

All DOCUMENTS and THINGS evidencing any oral or written communications CONCERNING the inventions claimed in PATENTS IN SUIT or any other U.S. or foreign patent, or U.S. or foreign patent application, including any provisional or abandoned application, that claims priority from or through, or through which priority is claimed by, the PATENTS IN SUIT, including without limitation laboratory notebooks, reports, or invention disclosure statements.

REQUEST NO. 32:

All DOCUMENTS and THINGS evidencing any oral or written communications CONCERNING the prosecution of the PATENTS IN SUIT or any other U.S. or foreign patent, or U.S. or foreign patent application, including any provisional or abandoned application, that claims priority from or through, or through which priority is claimed by, the PATENTS IN SUIT, including without limitation correspondence with U.S. or foreign patent offices, patent office actions, responses by applicants to patent office actions, attorney notes, attorney work product, notes of patent examiner interviews, and draft patent applications.

REQUEST NO. 33:

All DOCUMENTS and THINGS CONCERNING the Information Disclosure Statements, or supplements thereto, submitted in the prosecution of the PATENTS IN SUIT or any other U.S. or foreign patent, or U.S. or foreign patent application, including any provisional or abandoned application, that claims priority from or through, or through which priority is claimed by, the PATENTS IN SUIT, including without limitation documents, references and/or activities considered but not included in any Information Disclosure Statement, correspondence with U.S. or foreign patent offices, and attorney work product.

REQUEST NO. 34:

All DOCUMENTS and THINGS evidencing any oral or written communications CONCERNING EXTENDED RELEASE FORMULATIONS comprising VENLAFAXINE claimed in or covered by any U.S. or foreign patent, or U.S. or foreign patent application, including any provisional or abandoned application, by WYETH, including without limitation laboratory notebooks, reports, or invention disclosure statements.

REQUEST NO. 35:

All DOCUMENTS and THINGS evidencing any oral or written communications CONCERNING the prosecution by WYETH of the any U.S. or foreign patent, or U.S. or foreign patent application, including any provisional or abandoned application, that claims or covers EXTENDED RELEASE FORMULATIONS comprising VENLAFAXINE, including without limitation correspondence with U.S. or foreign patent offices, patent office actions, responses by applicants to patent office actions, attorney notes, attorney work product, notes of patent examiner interviews, and draft patent applications.

REQUEST NO. 36:

All DOCUMENTS and THINGS CONCERNING the Information Disclosure Statements, or supplements thereto, submitted during the prosecution by WYETH of the any U.S. or foreign patent, or U.S. or foreign patent application, including any provisional or abandoned application, that claims or covers EXTENDED RELEASE FORMULATIONS comprising VENLAFAXINE, including without limitation documents, references and/or activities considered but not included in any Information

Disclosure Statement, correspondence with U.S. or foreign patent offices, and attorney work product.

REQUEST NO. 37:

All DOCUMENTS and THINGS CONCERNING any unsuccessful or failed attempts to invent or create EXTENDED RELEASE FORMULATIONS comprising VENLAFAXINE, including without limitation laboratory notebooks, reports, or invention disclosure statements.

REQUEST NO. 38:

All DOCUMENTS and THINGS evidencing any oral or written communications CONCERNING the prosecution of U.S. Patent No. 4,535,186 or any other U.S. or foreign patent, or U.S. or foreign patent application, including any abandoned application, that claims priority from or through, or through which priority is claimed by, U.S. Patent No. 4,535,186, including without limitation correspondence with U.S. or foreign patent offices, patent office actions, responses by applicants to patent office actions, attorney notes, attorney work product, notes of patent examiner interviews, and draft patent applications.

REQUEST NO. 39:

All DOCUMENTS and THINGS evidencing any oral or written communications CONCERNING any U.S. or foreign patent, or U.S. or foreign patent application, including any abandoned application that describes, indicates, or claims the use of an EXTENDED RELEASE FORMULATION containing VENLAFAXINE, including without limitation correspondence with U.S. or foreign patent offices, patent office actions, responses by applicants to patent office actions, attorney notes, attorney work product, notes of patent examiner interviews, and draft patent applications.

REQUEST NO. 40:

All DOCUMENTS and THINGS evidencing any oral or written communications CONCERNING any U.S. or foreign patent, or U.S. or foreign patent application, including any abandoned application that describes, indicates, or claims the use of an EXTENDED RELEASE FORMULATION containing microcrystalline cellulose, including without limitation correspondence with U.S. or foreign patent offices, patent office actions, responses by applicants to patent office actions, attorney notes, attorney work product, notes of patent examiner interviews, and draft patent applications.

REQUEST NO. 41:

All DOCUMENTS and THINGS CONCERNING research, studies, or development of an EXTENDED RELEASE FORMULATION containing VENLAFAXINE, including without limitation laboratory notebooks, photos, clinical studies, clinical trials, patient records, publications, presentation materials, research notes, research files, diagrams, data and abstracts by the NAMED INVENTORS, and their collaborators including students, post doctoral fellows, colleagues, or others.

REQUEST NO. 42:

All DOCUMENTS and THINGS CONCERNING research, studies, or development of an EXTENDED RELEASE FORMULATION containing microcrystalline cellulose, including without limitation laboratory notebooks, photos, clinical studies, clinical trials, patient records, publications, presentation materials, research notes, research files, diagrams, data and abstracts by the NAMED INVENTORS, and their collaborators including students, post doctoral fellows, colleagues, or others.

REQUEST NO. 43:

ALL DOCUMENTS and THINGS CONCERNING the conception of the inventions claimed in the PATENTS IN SUIT or any other U.S. or foreign patent, or U.S. or foreign patent application including any abandoned application, that claims priority from or through the PATENTS IN SUIT, including without limitation laboratory notebooks, reports, or invention disclosure statements documenting or otherwise referring to the conception of the invention.

REQUEST NO. 44:

ALL DOCUMENTS and THINGS CONCERNING the first reduction to practice of the PATENTS IN SUIT or any other U.S. or foreign patent, or U.S. or foreign patent application including any abandoned application, that claims priority from or through the PATENTS IN SUIT, or any attempts to achieve such a reduction to practice, including without limitation laboratory notebooks, reports, or invention disclosure statements documenting or otherwise referring to the first reduction to practice.

REQUEST NO. 45:

ALL DOCUMENTS and THINGS CONCERNING the first sale or offer for sale of any product embodying any claim of the PATENTS IN SUIT, or EFFEXOR XR, including any invoices, purchase orders, receipts, bill of sales.

REQUEST NO. 46:

All invention disclosures made at any time by the NAMED INVENTORS CONCERNING an EXTENDED RELEASE FORMULATION containing VENLAFAXINE.

REQUEST NO. 47:

All DOCUMENTS and THINGS evidencing assignments, agreements, licenses, negotiations CONCERNING intellectual property rights or technology transfer between or among the NAMED INVENTORS and WYETH.

REQUEST NO. 48:

All DOCUMENTS and THINGS CONCERNING NDA 20-699, including without limitation submissions to the FDA, the listing of the PATENTS IN SUIT in the ORANGE BOOK, clinical trials, efficacy studies, and supplemental and related NDAs.

REQUEST NO. 49:

All DOCUMENTS and THINGS CONCERNING modifications made to the NDA 20-699, beginning with the initial experimentation through the current approval by the FDA, including without limitation laboratory notebooks, experimental or exploratory records, analytical profiles, analytical testing methods, specifications, certificates of analysis, correspondence, data, agreements, invention disclosures, and applications filed with any patent office that are now or have been at any time assigned to WYETH.

REQUEST NO. 50:

All DOCUMENTS and THINGS CONCERNING clinical studies 600B-208-US, 600B-209-US, 600B-367-EU, including without limitation clinical results, patient reports, corrected or amended reports, statistical analysis, records of incidence of nausea or emesis, laboratory notebooks, experimental or exploratory records, analytical profiles, analytical testing methods, specifications, certificates of analysis, correspondence, data, agreements, invention disclosures, and applications filed with any patent office that are now or have been at any time assigned to WYETH.

REQUEST NO. 51:

All DOCUMENTS and THINGS CONCERNING any INDIA for an EXTENDED RELEASE FORMULATION comprising VENLAFAXINE, including without limitation submissions to the FDA, or any modifications thereto.

REQUEST NO. 52:

All DOCUMENTS and THINGS CONCERNING public meetings anywhere in the world at which the NAMED INVENTORS; or any other PERSON presented orally or in writing information or research results or otherwise discussed an EXTENDED RELEASE FORMULATION comprising VENLAFAXINE, including without limitation all presentation materials, whether in written or electronic form, abstracts, notices and all other DOCUMENTS CONCERNING these presentations.

REQUEST NO. 53:

All publications, including articles in journals or magazines and contributions to textbooks or treatises, CONCERNING VENLAFAXINE, microcrystalline cellulose, or an EXTENDED RELEASE FORMULATION authored by the NAMED INVENTORS.

REQUEST NO. 54:

All DOCUMENTS and THINGS CONCERNING public meetings anywhere in the world at which the NAMED INVENTORS, or any other individual presented orally or in writing information or research results or otherwise discussed an EXTENDED RELEASE FORMULATION comprising microcrystalline cellulose, including without limitation all presentation materials, whether in written or electronic form, abstracts, notices and all other DOCUMENTS CONCERNING these presentations.

REQUEST NO. 55:

All DOCUMENTS and THINGS CONCERNING patents, patent applications, scientific literature, scientific articles, scientific publications, prior knowledge, public uses, sales, offers for sale, or any other prior art publications or activities CONCERNING an EXTENDED RELEASE FORMULATION comprising VENLAFAXINE of which the NAMED INVENTORS or WYETH is aware.

REQUEST NO. 56:

All DOCUMENTS and THINGS CONCERNING patents, patent applications, scientific literature, scientific articles, scientific publications, prior knowledge, public uses, sales, offers for sale, or any other prior art publications or activities CONCERNING an EXTENDED RELEASE FORMULATION comprising microcrystalline cellulose of which the NAMED INVENTORS or WYETH is aware.

REQUEST NO. 57:

All DOCUMENTS and THINGS CONCERNING the knowledge of the NAMED INVENTORS of U.S. Patent No. 3,954,959 and any patents, patent applications, or patent publications CONCERNING it.

REQUEST NO. 58:

All DOCUMENTS and THINGS CONCERNING the knowledge of the NAMED INVENTORS of U.S. Patent No. 4,138,475 or any patents, patent applications, or patent publications CONCERNING it.

REQUEST NO. 59:

All DOCUMENTS and THINGS CONCERNING the knowledge of the NAMED INVENTORS of U.S. Patent No. 4,369,172 or any patents, patent applications, or patent publications CONCERNING it.

REQUEST NO. 60:

All DOCUMENTS and THINGS CONCERNING the knowledge of the NAMED INVENTORS of U.S. Patent No. 4,535,186 or any patents, patent applications, or patent publications CONCERNING it.

REQUEST NO. 61:

All DOCUMENTS and THINGS CONCERNING the knowledge of the NAMED INVENTORS of U.S. Patent No. 4,966,768 or any patents, patent applications, or patent publications CONCERNING it.

REQUEST NO. 62:

All DOCUMENTS and THINGS CONCERNING the knowledge of the NAMED INVENTORS of U.S. Patent No. 5,506,270 or any patents, patent applications, or patent publications CONCERNING it.

REQUEST NO. 63:

All DOCUMENTS and THINGS CONCERNING the knowledge of the NAMED INVENTORS of U.S. Patent No. 5,552,429 or any patents, patent applications, or patent publications CONCERNING it.

REQUEST NO. 64:

All DOCUMENTS and THINGS CONCERNING the knowledge of the NAMED INVENTORS of Publication No. EP0654264 or any patents, patent applications, or patent publications CONCERNING it.

REQUEST NO. 65:

All DOCUMENTS and THINGS CONCERNING the knowledge of the NAMED INVENTORS of Publication No. EP0667150 or any patents, patent applications, or patent publications CONCERNING it.

REQUEST NO. 66:

All DOCUMENTS and THINGS CONCERNING the knowledge of the NAMED INVENTORS of Publication No. EP0797991 or any patents, patent applications, or patent publications CONCERNING it.

REQUEST NO. 67:

All DOCUMENTS and THINGS CONCERNING the knowledge of the NAMED INVENTORS of Publication No. WO/1994/027589 or any patents, patent applications, or patent publications CONCERNING it.

REQUEST NO. 68:

All DOCUMENTS and THINGS CONCERNING any analysis or discussion of inventorship for the PATENTS IN SUIT or for any non-issued, now abandoned patent applications for which any of the NAMED INVENTORS were at any time listed as an inventor.

REQUEST NO. 69:

All DOCUMENTS and THINGS CONCERNING any analysis or discussion of whether the PATENTS IN SUIT are valid, including without limitation opinions, prior art references, and prior art searches.

REQUEST NO. 70:

All DOCUMENTS and THINGS that support or contradict an assertion that the claims of the PATENTS IN SUIT are invalid for failing to meet the requirements of 35 U.S.C. sections 101, 102, 103, or 112.

REQUEST NO. 71:

All DOCUMENTS and THINGS that support or contradict an assertion that the claims of the PATENTS IN SUIT are invalid for non-joinder or mis-joinder in their inventorship group.

REQUEST NO. 72:

All DOCUMENTS and THINGS that support or contradict an assertion that the claims of the PATENTS IN SUIT are invalid for double patenting.

REQUEST NO. 73:

All DOCUMENTS and THINGS on which WYETH may rely to establish any secondary considerations of nonobviousness in connection with any of the inventions claimed in the PATENTS IN SUIT.

REQUEST NO. 74:

All DOCUMENTS and THINGS CONCERNING nausea, emesis, and any other side effects associated with the administration of immediate release VENLAFAXINE or EFFEXOR.

REQUEST NO. 75:

All DOCUMENTS and THINGS CONCERNING nausea, emesis, and any other side effects associated with the administration of an EXTENDED RELEASE FORMULATION containing VENLAFAXINE or EFFEXOR XR.

REQUEST NO. 76:

All DOCUMENTS and THINGS sufficient to IDENTIFY profits, sales, advertising expenditures, profit forecasts, sales forecasts, and advertising forecasts CONCERNING any products that embody any claims of the PATENTS IN SUIT or EFFEXOR XR, including without limitation profits, sales, advertising expenditures, profit forecasts, sales forecasts, and advertising forecasts on an annual and monthly basis.

REQUEST NO. 77:

All DOCUMENTS and THINGS sufficient to IDENTIFY profits, sales, advertising expenditures, profit forecasts, sales forecasts, and advertising forecasts CONCERNING EFFEXOR, including without limitation profits, sales, advertising expenditures, profit forecasts, sales forecasts, and advertising forecasts on an annual and monthly basis.

REQUEST NO. 78:

All DOCUMENTS and THINGS CONCERNING any WYETH policy, strategy, plan, or practice, whether formal or informal, stated or unstated, regarding patents,

including but not limited to filing patent applications, acquiring patents or patent applications from other persons, exploiting patents or patented technology, charging other persons with patent infringement, enforcing patents, licensing patents or patented technology, or cross-licensing patents or patented technology.

REQUEST NO. 79:

All DOCUMENTS and THINGS CONCERNING the need, desirability, or consideration of filing continuation-in-part applications, divisional applications, or continuation applications claiming priority in the PATENTS IN SUIT.

REQUEST NO. 80:

All DOCUMENTS and THINGS CONCERNING the need, desirability, consideration of any application for reissue or request for reexamination of the PATENTS IN SUIT.

REQUEST NO. 81:

All DOCUMENTS and THINGS CONCERNING the need, desirability, consideration of any any foreign patent application (including any application or request for reexamination or reissue of any foreign patent) in connection with any alleged invention covered by any claim of the PATENTS IN SUIT.

REQUEST NO. 82:

All DOCUMENTS and THINGS CONCERNING WYETH's document retention or document destruction policy, including but not limited to, all preservation memoranda or standard operating procedures relating to the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, or the above-captioned action.

REQUEST NO. 83:

All organizational charts of WYETH that list or include the NAMED INVENTORS.

REQUEST NO. 84:

All organizational charts of WYETH CONCERNING research, development, manufacturing, testing, production, assembly, distribution, sales, marketing, regulatory approval of EFFEXOR or EFFEXOR XR.

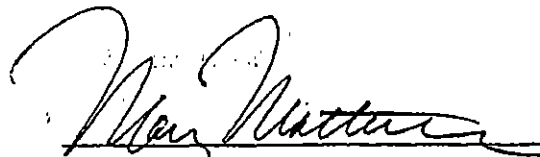
REQUEST NO. 85:

WYETH's annual reports to shareholders, annual and quarterly profit and loss statements, Form 10-K reports to the U.S. Securities and Exchange Commission, and any prospectus prepared or filed that CONCERNS EFFEXOR or EFFEXOR XR.

REQUEST NO. 86:

All DOCUMENTS and THINGS CONCERNING IMS data, Medco data, Scott-Levin audit data, or other data from third-party providers CONCERNING sales, prescriptions, or costs of EFFEXOR or EFFEXOR XR.

Dated: June 30, 2006



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EXHIBIT 7

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECEIVED
JUL 27 2006
RICHARD K. HERRMANN

WYETH,

Plaintiff,

v.

IMPAX LABORATORIES, INC.,

Defendant.

C. A. No. 06-222 (JJF)

**PLAINTIFF'S RESPONSES AND OBJECTIONS TO IMPAX'S FIRST
REQUEST FOR PRODUCTION OF DOCUMENTS AND THINGS (NOS. 1-4)**

Plaintiff, Wyeth, hereby responds to the First Request for Production of Documents and Things (Nos. 1-4) served by Defendant Impax Laboratories, Inc. (hereinafter "Impax") on June 23, 2006 via e-mail transmission and U.S. mail.

GENERAL OBJECTIONS

1. Wyeth objects to any request to the extent it seeks to impose on Wyeth any obligation not required by the Federal Rules of Civil Procedure or the local rules of the United States District Court for the District of Delaware.

2. Wyeth objects generally to the production of documents and things protected by the attorney-client privilege, work product immunity or any other applicable privilege. To the extent that such documents and things not otherwise objectionable are called for by Impax's requests, they will be identified in a listing of withheld documents which will be prepared in due course and exchanged with Impax on a mutually agreed upon date.

3. An objection based on attorney-client privilege and/or work product immunity should not be construed as a representation that such documents exist or existed. Such objections indicate only that the requests are of such a scope as to embrace subject matter protected by the attorney-client privilege and/or work product immunity.

4. Wyeth objects generally to Impax's document requests to the extent they seek production of documents and things containing both discoverable and non-discoverable or objectionable material. Wyeth reserves the right to redact any matter which is not called for or with respect to which Wyeth has objected to the request for production.

5. Wyeth objects to Impax's instructions to the extent they include within the definition of Wyeth's possession, custody or control all documents to which Wyeth has any access, however remote. Thus, Wyeth objects to Impax's document requests to the extent they seek to require Wyeth to provide any information beyond what is available to Wyeth at present from a reasonable search of its own files at its principal offices and pharmaceutical product research and development facilities in the United States and from reasonable inquiry of its present employees on the grounds that such discovery is irrelevant, unreasonably cumulative and unduly burdensome. Subject to these objections, Wyeth will use reasonable diligence to locate responsive documents in its possession, custody, and control based on an examination of those files reasonably expected to yield responsive documents.

6. As used in these responses, the phrase "all documents," or similar phrases, should be understood to mean those documents Wyeth and its counsel were

able to locate using reasonable diligence and judgment concerning the existence and whereabouts of responsive documents. Such phraseology should not be construed as a representation that each and every document available to Wyeth has been examined in connection with these responses or any production pursuant thereto.

7. Wyeth's objections and responses are based on the best knowledge and information known to them at this time. Wyeth's objections and responses are made without prejudice to Wyeth's right to revise or supplement them based on the discovery taken in this case. Further, Wyeth's objections and responses are based on Wyeth's good-faith interpretation of the individual requests for production and are subject to correction for errors or omission, if any.

8. Wyeth objects to the production of documents in the public domain because the burden of obtaining access to, copying, and production is equal for both parties. Subject to this General Objection, and to the extent not otherwise objectionable, Wyeth will not seek to exclude from production, responsive public documents within its possession, custody, and control.

9. A response that documents will be produced should not be construed as a representation that such documents exist or existed. Such responses indicate only that documents responsive to the request, subject to applicable objections, will be produced if any such documents are found after a reasonable search.

10. To the extent that Impax's document requests seek the production of internal work product files from any of Wyeth's counsel, including, but not limited to, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. and Morris, Nichols, Arsht &

Tunnell, L.L.P., Wyeth objects to either the production or the listing of these documents on a withheld document list.

11. Wyeth objects to the production of documents and things subject to the rights of third parties not affiliated with Wyeth. In addition, Wyeth objects to the production of non-Wyeth documents or information subject to a protective order entered in a litigation other than the above-captioned litigation.

12. Wyeth objects to Impax's definition of the term "Wyeth." This action involves Wyeth and not its past or present, U.S. or foreign subsidiaries, past or present, U.S. or foreign divisions, or "any related companies." In addition, Wyeth objects to Impax's definition of "Wyeth" to the extent it includes former officers, directors, employees, agents, attorneys or representatives as potentially including entities outside of Wyeth's possession, custody, or control, or calls for information that may be subject to confidentiality agreements and/or attorney-client privilege. Consequently, in answering Impax's requests, Wyeth will construe "Wyeth" to mean only those portions of Wyeth involved with the research and development, manufacture, distribution, and/or sale of the venlafaxine hydrochloride extended release product EFFEXOR® XR in the United States. Wyeth further objects to Impax's instructions as unduly burdensome to the extent they seek to impose any further limitations or obligations upon Wyeth with respect to the production of documents within Wyeth's possession, custody, or control than those set forth above.

13. Wyeth objects to the production of "electronically produced, electronically stored, photostatic, photographed, recorded, or otherwise reproduced communications or records of every kind and description," documents as well as "computer files,

including backup OR archival copies" as overly broad, unreasonably cumulative and unduly burdensome. Subject to the General and Specific Objections, Wyeth will agree to produce TIFF images of documents produced by Wyeth in the *Wyeth v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.* litigation, Civil Action No. 03-CV-1293 (WJM) (hereinafter "Teva litigation") that were obtained from searches of Wyeth's relevant electronic systems, assuming that Impax is willing to provide its produced documents, electronic or otherwise, to Wyeth in TIFF format, and that Impax reimburses Wyeth for half of the cost of imaging copies of documents previously imaged for the Teva litigation and for the full cost of imaging copies of any documents produced solely in this litigation. Alternatively, Wyeth is willing to produce documents to Impax in hard paper copy format and Impax can reimburse Wyeth for the cost of those copies.

14. Wyeth objects to Impax's requests to the extent they call for information (including listing on a withheld document log) or documents generated subsequent to the February 10, 2003 cut-off date observed in the Teva litigation as irrelevant, overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The production or listing on a withheld document log of any document or information generated subsequent to this date should not be construed as a waiver of this objection with respect to any other document or information.

15. The incidental production of any document or information covered by any of Wyeth's General or Specific Objections shall not be construed as a waiver of the objection with respect to any other document or information.

16. Nothing in these responses should be construed as waiving rights or objections which otherwise might be available to Wyeth, nor should Wyeth's answering any discovery request be deemed an admission of relevancy, materiality or admissibility in evidence of the discovery requests or the responses thereto.

17. The General Objections apply to all of Impax's Document Request Nos. 1-4. To the extent that specific General Objections are cited herein in response to specific document requests, those specific citations are provided because they are believed to be particularly applicable to the request and are not to be construed as a waiver of any other General Objections applicable to documents falling within the scope of the request.

18. Although Wyeth objects generally to Impax's request that documents and things be produced at the offices of Heller Ehrman, LLP, Wyeth will forward to the offices of Heller Ehrman, LLP copies of produced documents with the understanding that Heller Ehrman, LLP will promptly reimburse Wyeth for the cost of those copies and that Impax will similarly forward its produced copies to the offices of Finnegan Henderson. Nevertheless, Wyeth retains the right to produce documents or things by making them available for inspection and copying by Impax at Wyeth's or Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.'s facilities.

19. Until a protective order is entered in this litigation, any production of Wyeth's confidential documents is on an outside counsel eyes only basis pursuant to D. Del. L.R. 26.2.

20. Wyeth objects to Impax's Instructions 1 through 5 to the extent they seek to impose on Wyeth obligations not required by the Federal Rules of Civil Procedure or the local rules of the United States District Court for the District of Delaware.

IMPAX DOCUMENT REQUEST NO. 1:

All DOCUMENTS and things produced and in discovery by WYETH in *Wyeth v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.*, Civil Action No. 03-CV-1293 (WJM) before the United States District Court for the District of New Jersey.

OBJECTION:

Wyeth maintains the General and Specific Objections it made in response to requests for production propounded by Defendants in the Teva litigation and hereby incorporates by reference herein all of those General and Specific Objections and Responses. Wyeth further objects to this request to the extent it seeks all documents and things "produced and in discovery" as vague, ambiguous, and incomprehensible.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce all non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation, Civil Action No. 03-CV-1293 (WJM).

IMPAX DOCUMENT REQUEST NO. 2:

All DOCUMENTS related to requests for production propounded by Teva Pharmaceutical Industries Ltd. in *Wyeth v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.*, Civil Action No. 03-CV-1293 (WJM) before the United States District Court for the District of New Jersey, including but not limited to requests for production, responses and objections to requests for production, meet and confer letters regarding requests for production, and other correspondence regarding requests for production.

OBJECTION:

Wyeth objects to this request to the extent it seeks all documents "related to" requests for production as overly broad, vague and ambiguous, unduly burdensome, irrelevant, and not reasonably calculated to lead to the discovery of admissible

evidence. Wyeth further objects to this request to the extent it seeks "meet and confer letters" and "other correspondence" "regarding" requests for production as overly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this suit, and not reasonably calculated to lead to the discovery of admissible evidence. Furthermore, Wyeth objects to this request to the extent it seeks the production, or listing on a withheld document log, documents protected by the attorney-client privilege and/or work product immunity.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce requests for document production propounded by Teva Pharmaceuticals Industries Ltd. and Wyeth's responses and objections to requests for document production propounded by Teva Pharmaceuticals Ltd. to the extent they exist.

IMPAX DOCUMENT REQUEST NO. 3:

All transcripts of hearings AND depositions conducted in connection with *Wyeth v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.*, Civil Action No. 03-CV-1293 (WJM) before the United States District Court for the District of New Jersey, with those portions of the transcripts redacted that were designated as confidential by Defendant Teva Pharmaceuticals USA, Inc. AND/OR Teva Pharmaceutical Industries Ltd.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents and things subject to the rights of third parties not affiliated with Wyeth. Wyeth further objects to this request as unduly burdensome, overly broad, irrelevant to any issue in this suit and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks the production of deposition transcripts of Teva witnesses, or expert deposition

and/or hearing transcripts concerning infringement of products other than those at issue in this litigation and/or Teva confidential information. The Teva litigation involved a different Party and product, and information regarding that Party and product, is simply not relevant to this present litigation. Furthermore, Teva has designated the bulk of this information as confidential and subject to the protective order in place in the Teva litigation, and it would be unduly burdensome to attempt to redact this information. Moreover, under the protective order in that litigation, Teva, not Wyeth, would have to redact information it designated as confidential. Wyeth further objects to this request to the extent it requests transcripts of hearings regarding discovery disputes as overly broad, irrelevant to any issue in this lawsuit and not reasonably calculated to lead to the discovery of admissible evidence.

RESPONSE:

Subject to the General and Specific Objections above, Wyeth will produce transcripts of the depositions of Wyeth's fact witnesses in the Teva litigation.

IMPAX DOCUMENT REQUEST NO. 4:

All DOCUMENTS, including but not limited to exhibits, presentations, and demonstratives, introduced or used at hearings AND depositions conducted in connection with *Wyeth v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.*, Civil Action No. 03-CV-1293 (WJM) before the United States District Court for the District of New Jersey, with those portions of the DOCUMENTS redacted that were designated as confidential by Defendant Teva Pharmaceuticals USA, Inc. AND/OR Teva Pharmaceutical Industries, Ltd.

OBJECTION:

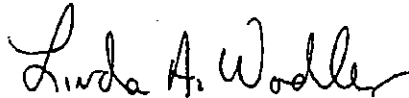
Wyeth objects to this request to the extent it seeks documents and things subject to the rights of third parties not affiliated with Wyeth. Wyeth further objects to this request as overly broad, vague and ambiguous, and irrelevant to any issue in this suit,

not reasonably calculated to lead to the discovery of admissible evidence and as potentially seeking the production of documents protected by the attorney-client privilege and/or work product immunity to the extent it seeks "all DOCUMENTS including but not limited to exhibits, presentations, and demonstratives . . . used." Wyeth further objects to this request as unduly burdensome, overly broad, irrelevant to any issue in this suit, and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks information concerning infringement of products other than those at issue in this litigation. The Teva litigation involved a different Party and product and information regarding that Party or product is simply not relevant to the present litigation. Furthermore, Teva has designated the bulk of this information as confidential and subject to the protective order in place in the Teva litigation, and it would be unduly burdensome to attempt to redact this information. Moreover, under the protective order in that litigation, Teva, not Wyeth, would have to redact information it designated as confidential. Wyeth further objects to this request as overly broad, vague and ambiguous, and as seeking documents protected by the attorney-client privilege and/or work product immunity, to the extent it requests information not produced to Teva, introduced at a deposition, or filed with the Court. Furthermore, Wyeth objects to this request to the extent it seeks the production, or listing on a withheld document log, documents protected by the attorney-client privilege and/or work product immunity.

RESPONSE:

Subject to the General and Specific Objections above, Wyeth will produce documents marked as exhibits by Teva or Wyeth during Teva's depositions of Wyeth fact witnesses in the Teva litigation.

Date: July 26, 2006



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Attorneys for Plaintiff Wyeth

CERTIFICATE OF SERVICE

I, Linda A. Wadler, hereby certify that on the 26th day of July, 2006, I caused true and correct copies of PLAINTIFF'S RESPONSES AND OBJECTIONS TO IMPAX'S FIRST REQUEST FOR PRODUCTION OF DOCUMENTS AND THINGS (NOS. 1-4) to be served by Federal Express, overnight delivery, upon the following:

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Dated: July 26, 2006
Washington, D.C.

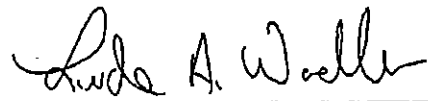

Linda A. Wadler

EXHIBIT 8

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECEIVED

AUG - 1 2006

RICHARD K. HERRMANN

WYETH,

Plaintiff,

v.

IMPAX LABORATORIES, INC.,

Defendant.

C. A. No. 06-222 (JJF)

**PLAINTIFF'S RESPONSES AND OBJECTIONS TO IMPAX'S SECOND
REQUEST FOR PRODUCTION OF DOCUMENTS AND THINGS (NOS. 5-86)**

Plaintiff, Wyeth, hereby responds to the First Request for Production of Documents and Things (Nos. 5-86) served by Defendant Impax Laboratories, Inc. (hereinafter "Impax") on June 30, 2006 via hand delivery.

GENERAL OBJECTIONS

1. Wyeth objects to any request to the extent it seeks to impose on Wyeth any obligation not required by the Federal Rules of Civil Procedure or the local rules of the United States District Court for the District of Delaware.

2. Wyeth objects generally to the production of documents and things protected by the attorney-client privilege, work product immunity, or any other applicable privilege. To the extent that such documents and things not otherwise objectionable are called for by Impax's requests, they will be identified in a listing of withheld documents which will be prepared in due course and exchanged with Impax on a mutually agreed upon date.

3. An objection based on attorney-client privilege and/or work product immunity should not be construed as a representation that such documents exist or existed. Such objections indicate only that the requests are of such a scope as to embrace subject matter protected by the attorney-client privilege and/or work product immunity.

4. Wyeth objects generally to Impax's document requests to the extent they seek production of documents and things containing both discoverable and nondiscoverable or objectionable material. Wyeth reserves the right to redact any matter which is not called for or with respect to which Wyeth has objected to the request for production.

5. Wyeth objects to Impax's instructions to the extent they include within the definition of Wyeth's possession, custody or control all documents to which Wyeth has any access, however remote. Thus, Wyeth objects to Impax's document requests to the extent they seek to require Wyeth to provide any information beyond what is available to Wyeth at present from a reasonable search of its own files at its principal offices and pharmaceutical product research and development facilities in the United States and from reasonable inquiry of its present employees on the grounds that such discovery is irrelevant, unreasonably cumulative and unduly burdensome. Subject to these objections, Wyeth will use reasonable diligence to locate responsive documents in its possession, custody, and control based on an examination of those files reasonably expected to yield responsive documents.

6. As used in these responses, the phrase "all documents," or similar phrases, should be understood to mean those documents Wyeth and its counsel were

able to locate using reasonable diligence and judgment concerning the existence and whereabouts of responsive documents. Such phraseology should not be construed as a representation that each and every document available to Wyeth has been examined in connection with these responses or any production pursuant thereto.

7. Wyeth's objections and responses are based on the best knowledge and information known to them at this time. Wyeth's objections and responses are made without prejudice to Wyeth's right to revise or supplement them based on the discovery taken in this case. Further, Wyeth's objections and responses are based on Wyeth's good-faith interpretation of the individual requests for production and are subject to correction for errors or omission, if any.

8. Wyeth objects to the production of documents in the public domain because the burden of obtaining access to, copying, and production is equal for both parties. Subject to this General Objection, and to the extent not otherwise objectionable, Wyeth will not seek to exclude from production, responsive public documents within its possession, custody, and control.

9. A response that documents will be produced should not be construed as a representation that such documents exist or existed. Such responses indicate only that documents responsive to the request, subject to applicable objections, will be produced if any such documents are found after a reasonable search.

10. To the extent that Impax's document requests seek the production of internal work product files from any of Wyeth's counsel, including, but not limited to, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. and Morris, Nichols, Arsht &

Tunnell, L.L.P., Wyeth objects to either the production or the listing of these documents on a withheld document list.

11. Wyeth objects to the production of documents and things subject to the rights of third parties not affiliated with Wyeth. In addition, Wyeth objects to the production of non-Wyeth documents or information subject to a protective order entered in a litigation other than the above-captioned litigation.

12. Wyeth objects to Impax's definition of the terms "Wyeth" or "Plaintiff." This action involves Wyeth and not its past or present, U.S. or foreign subsidiaries, past or present, U.S. or foreign divisions, or "any related companies." In addition, Wyeth objects to Impax's definition of "Wyeth" or "Plaintiff" to the extent these terms include former officers, directors, employees, agents, attorneys or representatives as potentially including entities outside of Wyeth's possession, custody, or control, and as calling for information that may be subject to confidentiality agreements and/or attorney-client privilege. Consequently, in answering Impax's requests, Wyeth will construe "Wyeth" and "Plaintiff" to mean only those portions of Wyeth involved with the research and development, manufacture, distribution, and/or sale of the venlafaxine hydrochloride extended release product EFFEXOR® XR in the United States. Wyeth further objects to Impax's instructions as unduly burdensome to the extent they seek to impose any further limitations or obligations upon Wyeth with respect to the production of documents within Wyeth's possession, custody, or control other than those set forth above.

13. Wyeth objects to the production of "electronically produced, electronically stored, photostatic, photographed, recorded, or otherwise reproduced communications

or records of every kind and description," documents as well as "computer files, including backup OR archival copies" as overly broad, unreasonably cumulative and unduly burdensome. Subject to the General and Specific Objections, Wyeth will agree to produce TIFF images of documents produced by Wyeth in the *Wyeth v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.* litigation, Civil Action No. 03-CV-1293 (WJM) (hereinafter "Teva litigation") that were obtained from searches of Wyeth's relevant electronic systems, assuming that Impax is willing to provide its produced documents, electronic or otherwise, to Wyeth in TIFF format, and that Impax reimburses Wyeth for half of the cost of imaging copies of documents previously imaged for the Teva litigation and for the full cost of imaging copies of any documents produced solely in this litigation. Alternatively, Wyeth is willing to produce documents to Impax in hard paper copy format and Impax can reimburse Wyeth for the cost of those copies.

14. Wyeth objects to Impax's requests to the extent they call for information (including listing on a withheld document log) or documents generated subsequent to the February 10, 2003 cut-off date observed in the Teva litigation as irrelevant, overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The production or listing on a withheld document log of any document or information generated subsequent to this date should not be construed as a waiver of this objection with respect to any other document or information.

15. Wyeth objects to the production of documents relating to ongoing clinical trials that are not complete and/or not decoded, analyzed, or reported. Wyeth further objects to the production of information such as voluminous raw data and data

compilations from *in vitro* testing, pre-clinical studies, or clinical trials as unduly burdensome, unreasonably cumulative, unreasonably duplicative and irrelevant.

16. Wyeth objects to the production of commercial, financial, regulatory, marketing, patent prosecution and proceedings, legal and other documents to the extent they concern countries other than the United States as unduly burdensome, overly broad, and/or irrelevant to any issue in the suit, and not reasonably calculated to lead to the discovery of admissible evidence.

17. Wyeth objects to the production of routine manufacturing, production, qualification, quality control, quality assurance, batch records, release records, and other routine testing as overly broad, irrelevant, unduly burdensome, unreasonably cumulative and duplicative, and not reasonably calculated to lead to the discovery of admissible evidence.

18. The incidental production of any document or information covered by any of Wyeth's General or Specific Objections shall not be construed as a waiver of the objection with respect to any other document or information.

19. Nothing in these responses should be construed as waiving rights or objections which otherwise might be available to Wyeth, nor should Wyeth's answering any discovery request be deemed an admission of relevancy, materiality or admissibility in evidence of the discovery requests or the responses thereto.

20. The General Objections apply to all of Impax's Document Request Nos. 5-86. To the extent that specific General Objections are cited herein in response to specific document requests, those specific citations are provided because they are believed to be particularly applicable to the request and are not to be construed as a

waiver of any other General Objections applicable to documents falling within the scope of the request.

21. Wyeth maintains the General and Specific Objections it made in response to requests for production propounded by Defendants in the Teva litigation and hereby incorporates by reference herein all of those General and Specific Objections and Responses.

22. Although Wyeth objects generally to Impax's request that documents and things be produced at the offices of Heller Ehrman, LLP, Wyeth will forward to the offices of Heller Ehrman, LLP copies of produced documents with the understanding that Heller Ehrman, LLP will promptly reimburse Wyeth for the cost of those copies and that Impax will similarly forward its produced copies to the offices of Finnegan Henderson. Nevertheless, Wyeth retains the right to produce documents or things by making them available for inspection and copying by Impax at Wyeth's or Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.'s facilities.

23. Until a protective order is entered in this litigation any production of Wyeth's confidential documents is on an outside counsel eyes only basis pursuant to D. Del. L.R. 26.2.

24. Wyeth objects to Impax's Instructions E (pages 5 and 6), F (pages 5 and 6), and G (2nd one) to the extent they seek to impose on Wyeth obligations not required by the Federal Rules of Civil Procedure or the local rules of the United States District Court for the District of Delaware and as overly burdensome.

25. Wyeth objects to Impax's definition of "named inventors" to the extent it encompasses persons beyond Deborah M. Sherman, John C. Clark, John U. Lamer

and Stephen A. White as vague and ambiguous, overly broad, unduly burdensome, and irrelevant to any issue in the suit.

RESPONSES

IMPAX DOCUMENT REQUEST NO. 5:

All DOCUMENTS and THINGS that were relied upon in responding to, or are identified in, WYETH's responses to Defendant Impax Laboratories, Inc.'s First Set of Interrogatories, served herewith.

OBJECTION:

Wyeth objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request to the extent it seeks all documents "relied upon in responding to" Impax's interrogatories as overly broad, vague and ambiguous, overly burdensome, and as irrelevant to any issue in this suit.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce the requested documents to the extent they are not protected by the attorney-client privilege and/or work product immunity.

IMPAX DOCUMENT REQUEST NO. 6:

All DOCUMENTS and THINGS identified in Plaintiff's Initial Disclosure Statement Pursuant to Fed. R. Civ. P. 26(a)(1), dated June 23, 2006, and any supplements or amendments thereto.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents that originated from Defendant, including but not limited to Impax's February 21, 2006 letter wherein Impax notified Wyeth that it had filed an ANDA seeking approval to market Venlafaxine HCl Extended-Release Capsules.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 7:

All DOCUMENTS and THINGS in the possession of Deborah M. Sherman CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

OBJECTION:

Wyeth objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request to the extent it seeks documents and things concerning "EFFEXOR" other than documents reflecting (1) comparisons between immediate release Effexor® and Effexor® XR, or (2) nausea and/or vomiting in humans associated with immediate release Effexor®.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 8:

All DOCUMENTS and THINGS in the possession of John C. Clark
CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and
clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

OBJECTION:

Wyeth objects to this request to the extent it seeks information protected by the
attorney-client privilege and/or work product immunity. Wyeth further objects to this
request to the extent it seeks documents and things concerning "EFFEXOR" other than
documents reflecting (1) comparisons between immediate release Effexor® and Effexor®
XR, or (2) nausea and/or vomiting in humans associated with immediate release
Effexor®.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce documents
and things previously produced by Wyeth in response to document requests in the Teva
litigation and will identify protected documents associated with that production on a
withheld document log.

IMPAX DOCUMENT REQUEST NO. 9:

All DOCUMENTS and THINGS in the possession of John U. Lamer
CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and
clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

OBJECTION:

Wyeth objects to this request to the extent it seeks information protected by the
attorney-client privilege and/or work product immunity. Wyeth further objects to this
request to the extent it seeks documents and things concerning "EFFEXOR" other than
documents reflecting (1) comparisons between immediate release Effexor® and Effexor®

XR, or (2) nausea and/or vomiting in humans associated with immediate release Effexor®.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 10:

All DOCUMENTS and THINGS in the possession of Stephen A. White CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

OBJECTION:

Wyeth objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request to the extent it seeks documents and things concerning "EFFEXOR" other than documents reflecting (1) comparisons between immediate release Effexor® and Effexor® XR, or (2) nausea and/or vomiting in humans associated with immediate release Effexor®.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 11:

All DOCUMENTS and THINGS in the possession of Rebecca R. Barrett CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

OBJECTION:

Wyeth objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request to the extent it seeks documents and things concerning "EFFEXOR" other than documents reflecting (1) comparisons between immediate release Effexor[®] and Effexor[®] XR, or (2) nausea and/or vomiting in humans associated with immediate release Effexor[®].

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 12:

All DOCUMENTS and THINGS in the possession of Egon E. Berg CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

OBJECTION:

Wyeth objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request to the extent it seeks documents from "the possession of Egon E. Berg" as encompassing documents outside of Wyeth's possession, custody and control. Wyeth

further objects to this request to the extent it seeks documents and things concerning "EFFEXOR" other than documents reflecting (1) comparisons between immediate release Effexor® and Effexor® XR, or (2) nausea and/or vomiting in humans associated with immediate release Effexor®.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 13:

All DOCUMENTS and THINGS in the possession of Steven R. Eck CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

OBJECTION:

Wyeth objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request to the extent it seeks documents from "the possession of Steven R. Eck" as encompassing documents outside of Wyeth's possession, custody and control. Wyeth further objects to this request to the extent it seeks documents and things concerning "EFFEXOR" other than documents reflecting (1) comparisons between immediate release Effexor® and Effexor® XR, or (2) nausea and/or vomiting in humans associated with immediate release Effexor®.

further objects to this request to the extent it seeks documents and things concerning "EFFEXOR" other than documents reflecting (1) comparisons between immediate release Effexor[®] and Effexor[®] XR, or (2) nausea and/or vomiting in humans associated with immediate release Effexor[®].

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 13:

All DOCUMENTS and THINGS in the possession of Steven R. Eck CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

OBJECTION:

Wyeth objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request to the extent it seeks documents from "the possession of Steven R. Eck" as encompassing documents outside of Wyeth's possession, custody and control. Wyeth further objects to this request to the extent it seeks documents and things concerning "EFFEXOR" other than documents reflecting (1) comparisons between immediate release Effexor[®] and Effexor[®] XR, or (2) nausea and/or vomiting in humans associated with immediate release Effexor[®].

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 14:

All DOCUMENTS and THINGS in the possession of Eliseo Salinas CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

OBJECTION:

Wyeth objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request to the extent it seeks documents from "the possession of Eliseo Salinas" as encompassing documents outside of Wyeth's possession, custody and control. Wyeth further objects to this request to the extent it seeks documents and things concerning "EFFEXOR" other than documents reflecting (1) comparisons between immediate release Effexor[®] and Effexor[®] XR, or (2) nausea and/or vomiting in humans associated with immediate release Effexor[®].

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 15:

All DOCUMENTS and THINGS in the possession of Joseph M. Mahady CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

OBJECTION:

Wyeth objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request to the extent it seeks documents and things concerning "EFFEXOR" other than documents reflecting (1) comparisons between immediate release Effexor[®] and Effexor[®] XR, or (2) nausea and/or vomiting in humans associated with immediate release Effexor[®].

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 16:

All DOCUMENTS and THINGS in the possession of Robin P. Enever CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

OBJECTION:

Wyeth objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request to the extent it seeks documents and things concerning "EFFEXOR" other than documents reflecting (1) comparisons between immediate release Effexor[®] and Effexor[®]

XR, or (2) nausea and/or vomiting in humans associated with immediate release Effexor®.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 17:

All DOCUMENTS and THINGS in the possession of Richard Deneale CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

OBJECTION:

Wyeth objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request to the extent it seeks documents from "the possession of Richard Deneale" as encompassing documents outside of Wyeth's possession, custody and control. Wyeth further objects to this request to the extent it seeks documents and things concerning "EFFEXOR" other than documents reflecting (1) comparisons between immediate release Effexor® and Effexor® XR, or (2) nausea and/or vomiting in humans associated with immediate release Effexor®.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 18:

All DOCUMENTS and THINGS in the possession of Dr. Mangano CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

OBJECTION:

Wyeth objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request to the extent it seeks documents and things concerning "EFFEXOR" other than documents reflecting (1) comparisons between immediate release Effexor® and Effexor® XR, or (2) nausea and/or vomiting in humans associated with immediate release Effexor®.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 19:

All DOCUMENTS and THINGS in the possession of Dr. Alaburda CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

OBJECTION:

Wyeth objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request as vague and ambiguous to the extent it seeks documents and things in the possession of "Dr. Alaburda." Wyeth further objects to this request to the extent it seeks documents and things concerning "EFFEXOR" other than documents reflecting (1)

comparisons between immediate release Effexor® and Effexor® XR, or (2) nausea and/or vomiting in humans associated with immediate release Effexor®.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 20:

All DOCUMENTS and THINGS in the possession of Richard Rudolph CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

OBJECTION:

Wyeth objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request to the extent it seeks documents from "the possession of Richard Rudolph" as encompassing documents outside of Wyeth's possession, custody and control. Wyeth further objects to this request to the extent it seeks documents and things concerning "EFFEXOR" other than documents reflecting (1) comparisons between immediate release Effexor® and Effexor® XR, or (2) nausea and/or vomiting in humans associated with immediate release Effexor®.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 21:

All DOCUMENTS and THINGS in the possession of Wilfredo Ortega-Leone CONCERNING the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, NDA 20-699, and clinical studies 600B-208-US, 600B-209-US, and 600B-367-EU.

OBJECTION:

Wyeth objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request to the extent it seeks documents and things concerning "EFFEXOR" other than documents reflecting (1) comparisons between immediate release Effexor[®] and Effexor[®] XR, or (2) nausea and/or vomiting in humans associated with immediate release Effexor[®].

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 22:

All DOCUMENTS and THINGS CONCERNING any claimed infringement of the PATENTS IN SUIT by IMPAX.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents that are protected by the attorney-client privilege and/or work product immunity and objects to the production or logging of such documents. To the extent that this request seeks the production of internal work product files from any of Wyeth's counsel, including, but not limited to, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. and Morris,

Nichols, Arsht & Tunnell, L.L.P., Wyeth objects to either the production or the listing of these documents on a withheld document list. Wyeth further objects to this request to the extent it seeks documents that are in Impax's possession, custody, or control. To the extent Impax is in possession, custody, or control of such documents, Wyeth has requested their production in this litigation.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce the requested documents to the extent they exist based upon a reasonable search and are not protected by the attorney-client privilege and/or work product immunity.

IMPAX DOCUMENT REQUEST NO. 23:

All DOCUMENTS and THINGS CONCERNING any claim by WYETH that IMPAX's alleged infringement was willful or that this is an exceptional case.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents that are protected by the attorney-client privilege and/or work product immunity and objects to the production or logging of such documents. To the extent that this request seeks the production of internal work product files from any of Wyeth's counsel, including, but not limited to, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. and Morris, Nichols, Arsht & Tunnell, L.L.P., Wyeth objects to either the production or the listing of these documents on a withheld document list. Wyeth further objects to this request to the extent it seeks documents that are in Impax's possession, custody, or control. To the extent Impax is in possession, custody, or control of such documents Wyeth has requested their production in this litigation.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce the requested documents to the extent they are not protected by the attorney-client privilege and/or work product immunity. Impax's February 21, 2006 letter to Wyeth is one such document, which Impax already has.

IMPAX DOCUMENT REQUEST NO. 24:

All intrinsic or extrinsic evidence on which WYETH intends to rely in construing the claims of the PATENTS IN SUIT.

OBJECTION:

Wyeth objects to this request as premature because the Court's Scheduling Order sets May 8, 2007 as the date when Opening Markman briefs are due. Further, Impax has refused to answer Wyeth Interrogatory No. 5 which seeks corresponding information that Impax intends to rely upon for its claim construction.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce the requested documents in accordance with the Scheduling Order adopted in this litigation.

IMPAX DOCUMENT REQUEST NO. 25:

All DOCUMENTS and THINGS that contradict or refute WYETH's construction or interpretation of the claims, claim elements, claim terms, or claim phrases of the PATENTS IN SUIT.

OBJECTION:

Wyeth further objects to this request as vague and ambiguous and not reasonably calculated to lead to the discovery of admissible evidence to the extent Impax has failed to define or differentiate between the terms "claims, claim elements,

claim terms, or claim phrases" and has failed to identify specific claim language. Wyeth objects to the production of documents and things subject to the rights of third parties not affiliated with Wyeth. In addition, Wyeth objects to the production of non-Wyeth documents subject to a protective order entered in a litigation other than the above-captioned litigation. Wyeth further objects to this request to the extent it requires Wyeth to review voluminous documents and make a subjective determination of what may or may not "contradict or refute" Wyeth's construction of the claims. Wyeth also objects to this request to the extent it calls for a legal conclusion in determining the documents that are responsive to the request.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 26:

ALL DOCUMENTS AND THINGS CONCERNING IMPAX'S VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE CAPSULE.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity. To the extent that this request seeks the production of internal work product files from any of Wyeth's counsel, including, but not limited to, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. and Morris, Nichols, Arsht & Tunnell, L.L.P., Wyeth objects to either the production or the listing of these documents on a withheld document list. Wyeth further objects to this

request to the extent it seeks documents that are in Impax's possession, custody, or control. To the extent Impax is in possession, custody, or control of such documents Wyeth has requested their production in this litigation.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce the requested documents to the extent they exist and are not protected by the attorney-client privilege and/or work product immunity.

IMPAX DOCUMENT REQUEST NO. 27:

All DOCUMENTS and THINGS CONCERNING any claimed infringement of the PATENTS IN SUIT by any PERSON other than IMPAX, including without limitation notice to the other PERSON, and responses by the other PERSON CONCERNING the PATENTS IN SUIT.

OBJECTION and RESPONSE:

Wyeth objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity and further objects to the logging of those withheld documents as overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. To the extent that this request seeks the production of internal work product files from any of Wyeth's counsel, including, but not limited to, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. and Morris, Nichols, Arsht & Tunnell, L.L.P., Wyeth objects to either the production or the listing of these documents on a withheld document list. Wyeth further objects to this request for documents concerning "any claimed infringement . . . by any PERSON other than IMPAX" to the extent it seeks documents and things not within Wyeth's possession, custody, or control. Because this request seeks documents concerning

infringement by third parties, the request is overly broad, unduly burdensome, irrelevant to any issue in this lawsuit, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth also objects to the production of documents and things subject to the rights of third parties not affiliated with Wyeth. In addition, Wyeth objects to the production of non-Wyeth documents or information subject to a protective order entered in a litigation other than the above-captioned litigation.

IMPAX DOCUMENT REQUEST NO. 28:

All DOCUMENTS and THINGS CONCERNING any litigation or other contested proceedings involving the PATENTS IN SUIT.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity and further objects to the logging of those withheld documents as overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. To the extent that this request seeks the production of internal work product files from any of Wyeth's counsel, including, but not limited to, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. and Morris, Nichols, Arsht & Tunnell, L.L.P., Wyeth objects to either the production or the listing of these documents on a withheld document list. Wyeth further objects to this request to the extent it seeks documents concerning "any litigation or other contested proceedings" as overly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this lawsuit, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request for documents concerning "any litigation or other contested proceedings" to the extent it seeks documents and

things not within Wyeth's possession, custody, or control. To the extent it seeks documents concerning infringement by third parties, the request is overly broad, unduly burdensome, irrelevant to any issue in this lawsuit, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth objects to the production of documents and things subject to the rights of third parties not affiliated with Wyeth. In addition, Wyeth objects to the production of non-Wyeth documents or information subject to a protective order entered in a litigation other than the above-captioned litigation.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log. Subject to the General and Specific Objections, Wyeth also will produce requests for document production propounded by the Defendants in the Teva litigation and Wyeth's responses and objections to those requests for document production, transcripts of the depositions of Wyeth's fact witnesses in the Teva litigation and documents marked as exhibits by Teva or Wyeth during Teva's depositions of Wyeth fact witnesses in the Teva litigation.

IMPAX DOCUMENT REQUEST NO. 29:

All pleadings and correspondence served by and between the parties in *Wyeth v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.*, Civil Action No. 03-CV-1293 (WJM) before the United States District Court for the District of New Jersey, including without limitation complaints, answers, replies to counterclaims, discovery requests and responses thereto, discovery dispute briefing and exhibits, motions, claim construction briefing and exhibits, and meet and confer letters regarding disputes between the parties.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents and things subject to the rights of third parties not affiliated with Wyeth. In addition, Wyeth objects to the production of non-Wyeth documents or information subject to a protective order entered in a litigation other than the above-captioned litigation. Wyeth further objects to this request as unduly burdensome, overly broad, irrelevant to any issue in this suit and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks the production of pleadings and correspondence concerning Teva witnesses, or pleadings and correspondence concerning infringement of products other than those at issue in this litigation. The Teva litigation involved a different Party and product, and information regarding that Party and product, is simply not relevant to this present litigation. Furthermore, Teva has designated the bulk of this information as confidential and subject to the protective order in place in the Teva litigation, and it would be unduly burdensome to attempt to redact this information. Moreover, under the protective order in that litigation, Teva, not Wyeth, would have to do the redaction of its own confidential information. Wyeth further objects to this request to the extent it requests "complaints, answers, replies to counterclaims, discovery requests and responses thereto, discovery dispute briefing and exhibits, motions, claim construction briefing and exhibits, and meet and confer letters regarding disputes between the parties" as overly broad, irrelevant to any issue in this lawsuit and not reasonably calculated to lead to the discovery of admissible evidence.

RESPONSE:

Subject to the General and Specific Objections above, Wyeth will produce requests for document production propounded by the Defendants in the Teva litigation and Wyeth's responses and objections to those requests for document production.

IMPAX DOCUMENT REQUEST NO. 30:

ALL DOCUMENTS and THINGS CONCERNING settlement of disputes regarding the infringement of, or licensing of, the PATENTS IN SUIT, including without limitation the settlement agreement between the parties in *Wyeth v. Teva Pharmaceuticals, USA, Inc. and Teva Pharmaceutical Industries Ltd.*, Civil Action No. 03-CV-1293 (WJM) before the United States District Court for the District of New Jersey, and negotiations regarding that dispute or disputes with other PERSON.

OBJECTION:

Wyeth objects to this interrogatory to the extent it seeks information protected by the attorney-client privilege and/or work product immunity and further objects to the logging of those withheld documents as overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this document request to the extent it seeks all documents and things concerning "settlement of disputes regarding the infringement of, or licensing of, the PATENTS IN SUIT" as irrelevant, highly confidential, competitive business information subject to the rights of third parties not affiliated with Wyeth, and as not reasonably calculated to lead to the discovery of admissible evidence. Wyeth also objects to this request to the extent it seeks documents and things subject to the rights of third parties not affiliated with Wyeth. In addition, Wyeth objects to the production of documents subject to a protective order entered in a litigation other than the above-captioned litigation. Wyeth further objects to this request as unduly burdensome, overly broad,

irrelevant to any issue in this suit and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks the production of documents relating to the settlement of disputes concerning infringement of products other than those at issue in this litigation. The Teva litigation involved a different Party and product, and information regarding that Party and product is simply not relevant to this present litigation. Furthermore, Teva has designated the bulk of this information as confidential and subject to the protective order in place in the Teva litigation, and it would be unduly burdensome to attempt to redact this information. Moreover, under the protective order in that litigation, Teva, not Wyeth, would have to do the redaction of its own confidential information. Wyeth further objects to this request to the extent it seeks documents concerning "negotiations" as overly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this lawsuit, not reasonably calculated to lead to the discovery of admissible evidence under the Federal Rules of Evidence. Wyeth further objects to this request to the extent it seeks documents available to Impax from the public domain, as unduly burdensome and unreasonable. Wyeth further objects to this request to the extent it seeks documents concerning "dispute or disputes with other PERSON" as vague and ambiguous, overly broad, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce publicly available documents regarding the settlement of the Teva litigation that it finds after a reasonable search of its own files.

IMPAX DOCUMENT REQUEST NO. 31:

All DOCUMENTS and THINGS evidencing any oral or written communications CONCERNING the inventions claimed in PATENTS IN SUIT or any other U.S. or foreign patent, or U.S. or foreign patent application, including any provisional or abandoned application, that claims priority from or through, or through which priority is claimed by, the PATENTS IN SUIT, including without limitation laboratory notebooks, reports, or invention disclosure statements.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity including but not limited to "invention disclosure statements." Wyeth further objects to this request to the extent it seeks documents evidencing any communications concerning the inventions claimed in "any other U.S. or foreign patent, or U.S. or foreign patent application, including any provisional or abandoned application, that claims priority from or through, or through which priority is claimed by, the PATENTS IN SUIT" as vague and ambiguous, overly broad, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request as seeking documents "evidencing any oral or written communications CONCERNING the inventions claimed" in the patents-in-suit as overly broad, unduly burdensome, irrelevant to any issue in the suit, unreasonably cumulative and duplicative, and not reasonably calculated to lead to the discovery of admissible evidence, to the extent the request seeks documents from the hundreds of Plaintiff's employees involved, for example, in routine testing, scale-up, maintenance, purchasing or qualification of raw materials and equipment, manufacturing, packaging, etc. Wyeth also objects to the production of voluminous raw data compilations gathered from, for

example, in vitro studies, pre-clinical studies, clinical trials, production runs, quality control procedures, and routine testing as unduly burdensome and unreasonably cumulative and duplicative.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log. In addition, subject to the General and Specific Objections, Wyeth will produce the transcripts of the depositions of Wyeth's fact witnesses in the Teva litigation and documents marked as exhibits by Teva or Wyeth during Teva's depositions of Wyeth fact witnesses in the Teva litigation.

IMPAX DOCUMENT REQUEST NO. 32:

All DOCUMENTS and THINGS evidencing any oral or written communications CONCERNING the prosecution of the PATENTS IN SUIT or any other U.S. or foreign patent, or U.S. or foreign patent application, including any provisional or abandoned application, that claims priority from or through, or through which priority is claimed by, the PATENTS IN SUIT, including without limitation correspondence with U.S. or foreign patent offices, patent office actions, responses by applicants to patent office actions, attorney notes, attorney work product, notes of patent examiner interviews, and draft patent applications.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity, including but not limited to "attorney notes, attorney work product," and "draft patent applications." Wyeth further objects to this request to the extent it seeks documents concerning "any oral or written

communications CONCERNING the prosecution of . . . any other U.S. or foreign patent, or U.S. or foreign patent application that claims priority from or through, or through which priority is claimed by, the PATENTS IN SUIT" as overly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this lawsuit, and not reasonably calculated to lead to the discovery of admissible evidence.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 33:

All DOCUMENTS and THINGS CONCERNING the Information Disclosure Statements, or supplements thereto, submitted in the prosecution of the PATENTS IN SUIT or any other U.S. or foreign patent, or U.S. or foreign patent application, including any provisional or abandoned application, that claims priority from or through, or through which priority is claimed by, the PATENTS IN SUIT, including without limitation documents, references and/or activities considered but not included in any Information Disclosure Statement, correspondence with U.S. or foreign patent offices, and attorney work product.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity including but not limited to "attorney work product." Wyeth further objects to this request to the extent it seeks documents concerning "prosecution of . . . any other U.S. or foreign patent, or U.S. or foreign patent application, including any provisional or abandoned application, that claims priority from or through, or through which priority is claimed by, the PATENTS IN

SUIT" as overly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this lawsuit, and not reasonably calculated to lead to the discovery of admissible evidence.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 34:

All DOCUMENTS and THINGS evidencing any oral or written communications CONCERNING EXTENDED RELEASE FORMULATIONS comprising VENLAFAXINE claimed in or covered by any U.S. or foreign patent, or U.S. or foreign patent application, including any provisional or abandoned application, by WYETH, including without limitation laboratory notebooks, reports, or invention disclosure statements.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity, including but not limited to invention disclosure statements. Wyeth further objects to this request to the extent it seeks communications concerning extended release formulations of venlafaxine "claimed in or covered by any U.S. or foreign patent, or U.S. or foreign patent application, including any provisional or abandoned application, by WYETH" as overly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this lawsuit, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it seeks documents concerning patents and patent applications other than the patents-in-suit as vague and ambiguous,

overly broad, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it seeks documents regarding highly sensitive future products. Wyeth further objects to this request to the extent it seeks documents concerning any venlafaxine-containing extended release formulation developed after the effective filing date of the patents-in-suit other than EFFEXOR® XR as overly broad, unduly burdensome, irrelevant to any issue in the suit, not reasonably calculated to lead to the discovery of admissible evidence and as seeking highly sensitive future product information.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 35:

All DOCUMENTS and THINGS evidencing any oral or written communications CONCERNING the prosecution by WYETH of any of the U.S. or foreign patent, or U.S. or foreign patent application, including any provisional or abandoned application, that claims or covers EXTENDED RELEASE FORMULATIONS comprising VENLAFAXINE, including without limitation correspondence with U.S. or foreign patent offices, patent office actions, responses by applicants to patent office actions, attorney notes, attorney work product, notes of patent examiner interviews, and draft patent applications.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity, including but not limited to "attorney notes, attorney work product" and "draft patent applications." Wyeth further

objects to this request to the extent it seeks documents evidencing communications concerning the prosecution by Wyeth of "any of the U.S. or foreign patent, or U.S. or foreign patent application, including any provisional or abandoned application, that claims or covers EXTENDED RELEASE FORMULATIONS comprising VENLAFAXINE" as overly broad, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it seeks publicly available files relating to patents and patent applications as unduly burdensome because the burden on Impax is no more than the burden on Wyeth to obtain those documents.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things relating to the prosecution of the patents in suit previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 36:

All DOCUMENTS and THINGS CONCERNING the Information Disclosure Statements, or supplements thereto, submitted during the prosecution by WYETH of any of the U.S. or foreign patent, or U.S. or foreign patent application, including any provisional or abandoned application, that claims or covers EXTENDED RELEASE FORMULATIONS comprising VENLAFAXINE, including without limitation documents, references and/or activities considered but not included in any Information Disclosure Statement, correspondence with U.S. or foreign patent offices, and attorney work product.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity, including but not limited to "attorney work product." Wyeth further objects to this request to the extent it seeks documents concerning "any of the U.S. or foreign patent, or U.S. or foreign patent application, including any provisional or abandoned application, that claims or covers EXTENDED RELEASE FORMULATIONS comprising VENLAFAXINE" as concerning patents and patent applications other than the patents-in-suit and therefore overly broad, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things relating to the prosecution of the patents in suit previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 37:

All DOCUMENTS and THINGS CONCERNING any unsuccessful or failed attempts to invent or create EXTENDED RELEASE FORMULATIONS comprising VENLAFAXINE, including without limitation laboratory notebooks, reports, or invention disclosure statements.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents concerning "any unsuccessful attempts to invent or create" as overly broad and vague and ambiguous.

Wyeth further objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity, including but not limited to "invention disclosure statements." Wyeth further objects to this request to the extent it seeks documents concerning any "EXTENDED RELEASE FORMULATIONS" to the extent it encompasses formulations developed after the effective filing date of the patents in suit as overly broad, unduly burdensome, irrelevant to any issue in the suit, not reasonably calculated to lead to the discovery of admissible evidence and as seeking highly sensitive future product information.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 38:

All DOCUMENTS and THINGS evidencing any oral or written communications CONCERNING the prosecution of U.S. Patent No. 4,535,186 or any other U.S. or foreign patent, or U.S. or foreign patent application, including any abandoned application, that claims priority from or through, or through which priority is claimed by, U.S. Patent No. 4,535,186, including without limitation correspondence with U.S. or foreign patent offices, patent office actions, responses by applicants to patent office actions, attorney notes, attorney work product, notes of patent examiner interviews, and draft patent applications.

OBJECTION AND RESPONSE:

Wyeth objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity including but not limited to "attorney notes, attorney work product," and "draft patent applications." Wyeth further

objects to this request to the extent it seeks any communications concerning "the prosecution of U.S. Patent No. 4,535,186 or any other U.S. or foreign patent, or U.S. or foreign patent application, including any abandoned application, that claims priority from or through, or through which priority is claimed by, U.S. Patent No. 4,535,186" and correspondence with . . . foreign patent offices" as overly broad, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence.

IMPAX DOCUMENT REQUEST NO. 39:

All DOCUMENTS and THINGS evidencing any oral or written communications CONCERNING any U.S. or foreign patent, or U.S. or foreign patent application, including any abandoned application that describes, indicates, or claims the use of an EXTENDED RELEASE FORMULATION containing VENLAFAXINE, including without limitation correspondence with U.S. or foreign patent offices, patent office actions, responses by applications to patent office actions, attorney notes, attorney work product, notes of patent examiner interviews, and draft patent applications.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity, including but not limited to "attorney notes," "attorney work product," and "draft patent applications." Wyeth further objects to this request to the extent it seeks any communications concerning "any U.S. or foreign patent, or U.S. or foreign patent application, including any abandoned application that describes, indicates, or claims the use of an EXTENDED RELEASE FORMULATION containing VENLAFAXINE" encompassing documents concerning patents and patent applications other than the patents-in-suit as vague and ambiguous, overly broad, unduly burdensome, irrelevant to any issue in this litigation, and not

reasonably calculated to lead to the discovery of admissible evidence and as seeking highly sensitive future product information. Wyeth further objects to this request to the extent it seeks publicly available patents and patent applications as unduly burdensome because the burden on Impax is no more than the burden on Wyeth to obtain those documents. To the extent Impax's request would require Wyeth to search through publicly available literature, this request is unduly burdensome and unreasonable. Such printed publications are already available to Impax and Impax can search for such documents on its own.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 40:

All DOCUMENTS and THINGS evidencing any oral or written communications CONCERNING any U.S. or foreign patent; or U.S. or foreign patent application, including any abandoned application that describes, indicates, or claims the use of an EXTENDED RELEASE FORMULATION containing microcrystalline cellulose, including without limitation correspondence with U.S. or foreign patent offices, patent office actions, responses by applicants to patent office actions, attorney notes, attorney work product, notes of patent examiner interviews, and draft patent applications.

OBJECTION and RESPONSE:

Wyeth objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity including but not limited to "attorney notes, attorney work product," and "draft patent applications." Wyeth further

objects to this request to the extent it seeks any communications concerning "any U.S. or foreign patent, or U.S. or foreign patent application, including any abandoned application that describes, indicates, or claims the use of an EXTENDED RELEASE FORMULATION containing microcrystalline cellulose" encompassing documents concerning patents and patent applications other than the patents-in-suit as vague and ambiguous, overly broad, unduly burdensome, irrelevant to any issue in this litigation, not reasonably calculated to lead to the discovery of admissible evidence and as seeking highly sensitive product information. Wyeth further objects to this request as literally encompassing formulations that do not even contain venlafaxine. Wyeth further objects to this request to the extent it seeks publicly available patents and patent applications as unduly burdensome because the burden on Impax is no more than the burden on Wyeth to obtain those documents. To the extent Impax's request would require Wyeth to search through publicly available literature, this request is unduly burdensome and unreasonable. Such printed publications are already available to Impax and Impax can search for such documents on its own.

IMPAX DOCUMENT REQUEST NO. 41:

All DOCUMENTS and THINGS CONCERNING research, studies, or development of an EXTENDED RELEASE FORMULATION containing VENLAFAXINE, including without limitation laboratory notebooks, photos, clinical studies, clinical trials, patient records, publications, presentation materials, research notes, research files, diagrams, data and abstracts by the NAMED INVENTORS, and their collaborators including students, post doctoral fellows, colleagues, or others.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents and things concerning research, studies, or development of an "EXTENDED RELEASE FORMULATION containing VENLAFAXINE" developed after the effective filing date of

the patents in suit other than Effexor[®] XR as overly broad, unduly burdensome, not reasonably calculated to lead to the discovery of admissible evidence and as seeking highly sensitive future product information. Wyeth further objects to this request as irrelevant, overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents from the hundreds of Plaintiff's employees involved, for example, in routine testing, scale-up, maintenance, purchasing or qualification of raw materials and equipment, manufacturing, packaging, etc. Wyeth also objects to the production of voluminous raw data compilations gathered from, for example, in vitro studies, pre-clinical studies, clinical trials, production runs, quality control procedures, and routine testing as unduly burdensome and unreasonably cumulative and duplicative. Wyeth further objects to this request to the extent it seeks documents from "collaborators including students, post doctoral fellows, colleagues, or others" as encompassing documents outside of Wyeth's possession, custody and control. Wyeth further objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 42:

All DOCUMENTS and THINGS CONCERNING research, studies, or development of an EXTENDED RELEASE FORMULATION containing microcrystalline cellulose, including without limitation laboratory notebooks, photos, clinical studies, clinical trials, patient records, publications, presentation materials, research notes, research files, diagrams, data and abstracts by the NAMED INVENTORS, and their collaborators including students, post doctoral fellows, colleagues, or others.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents and things concerning research, studies, or development of an "EXTENDED RELEASE FORMULATION containing microcrystalline cellulose" as overly broad, unduly burdensome, irrelevant, not reasonably calculated to lead to the discovery of admissible evidence, and as seeking highly sensitive future product information. Wyeth further objects to this request as literally encompassing formulations that do not even contain venlafaxine. Wyeth further objects to this request as irrelevant, overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence to the extent it seeks documents from the hundreds of Plaintiff's employees involved, for example, in routine testing, scale-up, maintenance, purchasing or qualification of raw materials and equipment, manufacturing, packaging, etc. Wyeth also objects to the production of voluminous raw data compilations gathered from, for example, in vitro studies, pre-clinical studies, clinical trials, production runs, quality control procedures, and routine testing as unduly burdensome and unreasonably cumulative and duplicative. Wyeth further objects to this request to the extent it seeks documents from "collaborators including students, post doctoral fellows, colleagues, or others" as encompassing documents outside of Wyeth's possession, custody and control and/or subject to the rights of third parties. Wyeth further objects to this request

to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 43:

All DOCUMENTS and THINGS CONCERNING the conception of the inventions claimed in the PATENTS IN SUIT or any other U.S. or foreign patent, or U.S. or foreign patent application including any abandoned application, that claims priority from or through the PATENTS IN SUIT, including without limitation laboratory notebooks, reports, or invention disclosure statements documenting or otherwise referring to the conception of the invention.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents that are protected by the attorney-client privilege and/or work product immunity including but not limited to "invention disclosure statements." Wyeth further objects to this request to the extent it seeks documents concerning "any other U.S. or foreign patent, or U.S. or foreign patent application including any abandoned application, that claims priority from or through the PATENTS IN SUIT" as vague and ambiguous, overly broad, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it seeks documents "otherwise referring to the conception of the invention" as overly

broad, vague and ambiguous, unduly burdensome, and not calculated to lead to the discovery of admissible evidence.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 44:

All DOCUMENTS and THINGS CONCERNING the first reduction to practice of the PATENTS IN SUIT or any other U.S. or foreign patent, or U.S. or foreign patent application including any abandoned application, that claims priority from or through the PATENTS IN SUIT, or any attempts to achieve such a reduction to practice, including without limitation laboratory notebooks, reports, or invention disclosure statements documenting or otherwise referring to the first reduction to practice.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents that are protected by the attorney-client privilege and/or work product immunity, including but not limited to "invention disclosure statements." Wyeth further objects to this request to the extent it seeks documents concerning "any other U.S. or foreign patent, or U.S. or foreign patent application including any abandoned application, that claims priority from or through the PATENTS IN SUIT" as vague and ambiguous, overly broad, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it seeks documents "otherwise referring to the first reduction to practice" as overly broad, vague and ambiguous, unduly burdensome, and not calculated to lead to the discovery

of admissible evidence. Wyeth further objects to the production of voluminous raw data compilations gathered from, for example, clinical trials as unduly burdensome and unreasonably cumulative and duplicative.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 45:

All DOCUMENTS and THINGS CONCERNING the first sale or offer for sale of any product embodying any claim of the PATENTS IN SUIT, or EFFEXOR XR, including any invoices, purchase orders, receipts, bill of sales.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents that are protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request to the extent the phrase "any product embodying" encompasses any venlafaxine-containing product other than EFFEXOR® XR sold or offered for sale after the effective filing date of the patents-in-suit as vague and ambiguous, overly broad, unduly burdensome, irrelevant to any issue in the suit, not reasonably calculated to lead to the discovery of admissible evidence and as seeking highly sensitive future product information. Wyeth further objects to this request to the extent it seeks "all" documents and things, "including any invoices, purchase orders, receipts, bill of sales" as overly broad, unduly burdensome, irrelevant to any issue in the suit, and not reasonably calculated to lead to the discovery of admissible evidence.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 46:

All invention disclosures made at any time by the NAMED INVENTORS CONCERNING an EXTENDED RELEASE FORMULATION containing VENLAFAXINE.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents that are protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request to the extent it seeks documents concerning an "EXTENDED RELEASE FORMULATION containing VENLAFAXINE" developed after the effective filing date of the patents in suit other than Effexor® XR as overly broad, unduly burdensome, irrelevant to any issue in the suit, not reasonably calculated to lead to the discovery of admissible evidence and as seeking highly sensitive future product information.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will identify protected documents concerning any invention disclosures for the patents in suit on a withheld document list.

IMPAX DOCUMENT REQUEST NO. 47:

All DOCUMENTS and THINGS evidencing assignments, agreements, licenses, negotiations CONCERNING intellectual property rights or technology transfer between or among the NAMED INVENTORS and WYETH.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request to the extent it seeks documents concerning "intellectual property rights or technology transfer" other than the patents in suit as vague and ambiguous, overly broad, unduly burdensome, irrelevant to any issue in the suit, not reasonably calculated to lead to the discovery of admissible evidence and as seeking highly sensitive product information.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 48:

All DOCUMENTS and THINGS CONCERNING NDA 20-699, including without limitation submissions to the FDA, the listing of the PATENTS IN SUIT in the ORANGE BOOK, clinical trials, efficacy studies, and supplemental and related NDAs.

OBJECTION:

Wyeth objects to this request to the extent it seeks any documents whatsoever "CONCERNING NDA 20-699" as overly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence. For example, Wyeth objects to this request as overly broad, unduly burdensome and irrelevant to any issue in this litigation to the extent it seeks documents concerning the manufacture of venlafaxine

hydrochloride itself, specifications and analytical methods for venlafaxine hydrochloride itself, batch records, stability, toxicology, packaging, quality control, plant layouts, raw patient data from which patient identifying information must be redacted, etc. Wyeth also objects to this request to the extent it seeks "related NDAs" as overly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log. Those documents include, *inter alia*, a complete copy of the Table of Contents for New Drug Application (NDA) No. 20-699 as well as portions of the following sections of NDA No. 20-699: Chemistry Manufacturing and Controls, Labeling, Human Pharmacokinetics and Bioavailability, Clinical, Safety Update, Patent and Exclusivity Information and Patent Certification Information.

IMPAX DOCUMENT REQUEST NO. 49:

All DOCUMENTS and THINGS CONCERNING modifications made to the NDA 20-699, beginning with the initial experimentation through the current approval by the FDA, including without limitation laboratory notebooks, experimental or exploratory records, analytical profiles, analytical testing methods, specifications, certificates of analysis, correspondence, data, agreements, invention disclosures, and applications filed with any patent office that are now or have been at any time assigned to WYETH.

OBJECTION:

Wyeth objects to this request to the extent it seeks any documents whatsoever "CONCERNING modifications made to the NDA 20-699" as overly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence. For example, Wyeth objects to this request as overly broad, unduly burdensome and irrelevant to any issue in this litigation to the extent it seeks documents concerning the manufacture of venlafaxine hydrochloride itself, specifications and analytical methods for venlafaxine hydrochloride itself, batch records, stability, toxicology, packaging, quality control, plant layouts, raw patient data from which patient identifying information must be redacted, etc. Wyeth further objects to this request to the extent it seeks "applications filed with any patent office that are now or have been at anytime assigned to Wyeth" as unduly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this litigation, boundless and meaningless in the context of this request, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it seeks publicly available files relating to patents and patent applications as unduly burdensome because the burden on Impax is no more than the burden on Wyeth to obtain those documents. Wyeth further objects to this request to

the extent it seeks documents protected by the attorney-client privilege and/or work product immunity, including but not limited to "invention disclosures."

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log. Those documents include, *inter alia*, a complete copy of the Table of Contents for New Drug Application (NDA) No. 20-699 as well as portions of the following sections of NDA No. 20-699: Chemistry Manufacturing and Controls, Labeling, Human Pharmacokinetics and Bioavailability, Clinical, Safety Update, Patent and Exclusivity Information and Patent Certification Information.

IMPAX DOCUMENT REQUEST NO. 50:

All DOCUMENTS and THINGS CONCERNING clinical studies 600B-208-US, 600B-209-US, 600B-367-EU, including without limitation clinical results, patient reports, corrected or amended reports, statistical analysis, records of incidence of nausea or emesis, laboratory notebooks, experimental or exploratory records, analytical profiles, analytical testing methods, specifications, certificates of analysis, correspondence, data, agreements, invention disclosures, and applications filed with any patent office that are now or have been at any time assigned to WYETH.

OBJECTION:

Wyeth objects to this request to the extent it seeks any documents whatsoever "CONCERNING clinical studies 600B-208-US, 600B-209-US, 600B-367-EU" as overly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence

to the extent it seeks the production of voluminous raw data and data compilations as well as raw patient data from which patient identifying information must be redacted, etc. Wyeth further objects to this request to the extent it seeks "applications filed with any patent office that are now or have been at anytime assigned to Wyeth" as unduly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this litigation, boundless and meaningless in the context of this request, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it seeks publicly available files relating to patents and patent applications as unduly burdensome because the burden on Impax is no more than the burden on Wyeth to obtain those documents. Wyeth further objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity, including but not limited to "invention disclosures."

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 51:

All DOCUMENTS and THINGS CONCERNING any INDA for an EXTENDED RELEASE FORMULATION comprising VENLAFAXINE, including without limitation submissions to the FDA, or any modifications thereto.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents "CONCERNING any INDA for an EXTENDED RELEASE FORMULATION comprising VENLAFAXINE"

as overly broad, unduly burdensome, irrelevant to any issue in the suit and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it seeks documents concerning INDAs other than INDA No. 41,412 as vague and ambiguous, overly broad, unduly burdensome, irrelevant to any issue in the suit, not reasonably calculated to lead to the discovery of admissible evidence and as seeking highly sensitive future product information. Wyeth further objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 52:

All DOCUMENTS and THINGS CONCERNING public meetings anywhere in the world at which the NAMED INVENTORS, or any other PERSON presented orally or in writing information or research results or otherwise discussed an EXTENDED RELEASE FORMULATION comprising VENLAFAXINE, including without limitation all presentation materials, whether in written or electronic form, abstracts, notices and all other DOCUMENTS CONCERNING these presentations.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents concerning "public meetings anywhere in the world" regarding "an EXTENDED RELEASE FORMULATION comprising VENLAFAXINE" as overly broad, unduly burdensome, irrelevant to any issue in the suit, not reasonably calculated to lead to the discovery of admissible

evidence. Wyeth further objects to this request to the extent it seeks documents concerning "any other PERSON" as vague and ambiguous, overly broad, unduly burdensome, irrelevant to any issue in the suit, not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it seeks documents concerning "any other PERSON" insofar as it seeks documents and things not within Wyeth's possession, custody, or control and/or subject to the rights of third parties not affiliated with Wyeth. To the extent Impax's request would require Wyeth to search through publicly available literature or seeks documents available to Impax from the public domain, this request is overly broad, unduly burdensome and unreasonable. Such printed publications are already available to Impax and Impax can search for such documents on its own. Wyeth objects to Impax's definition of "named inventors" to the extent it encompasses persons beyond Deborah M. Sherman, John C. Clark, John U. Lamer and Stephen A. White as vague and ambiguous, overly broad, unduly burdensome, and irrelevant to any issue in the suit. Wyeth further objects to this request to the extent it seeks documents concerning public meetings at which "an EXTENDED RELEASE FORMULATION comprising VENLAFAXINE" was "otherwise discussed" as overly broad, unduly burdensome and unreasonable. Wyeth further objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to

document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 53:

All publications, including articles in journals or magazines and contributions to textbooks or treatises, CONCERNING VENLAFAXINE, microcrystalline cellulose, or an EXTENDED RELEASE FORMULATION authored by the NAMED INVENTORS.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents concerning "VENLAFAXINE, microcrystalline cellulose, or an EXTENDED RELEASE FORMULATION" as overly broad, unduly burdensome, irrelevant to any issue in the suit, not reasonably calculated to lead to the discovery of admissible evidence. Wyeth objects to Impax's definition of "named inventors" to the extent it encompasses persons beyond Deborah M. Sherman, John C. Clark, John U. Lamer and Stephen A. White as vague and ambiguous, overly broad, unduly burdensome, and irrelevant to any issue in the suit. Wyeth further objects to this request to the extent it seeks publicly available publications as unduly burdensome because the burden on Impax is no more than the burden on Wyeth to obtain those documents. To the extent Impax's request would require Wyeth to search through publicly available literature, this request is unduly burdensome and unreasonable. Such printed publications are already available to Impax and Impax can search for such documents on its own.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to

document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 54:

All DOCUMENTS and THINGS CONCERNING public meetings anywhere in the world at which the NAMED INVENTORS, or any other individual presented orally or in writing information or research results or otherwise discussed an EXTENDED RELEASE FORMULATION comprising microcrystalline cellulose, including without limitation all presentation materials, whether in written or electronic form, abstracts, notices and all other DOCUMENTS CONCERNING these presentations.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents concerning public meetings anywhere in the world" regarding "EXTENDED RELEASE FORMULATION comprising microcrystalline cellulose" as overly broad, unduly burdensome, irrelevant to any issue in the suit, not reasonably calculated to lead to the discovery of admissible evidence and as seeking highly sensitive product information. Wyeth further objects to this request to the extent it seeks documents concerning "any other individual" as vague and ambiguous, overly broad, unduly burdensome, irrelevant to any issue in the suit, not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it seeks documents concerning "any other individual" insofar as it seeks documents and things not within Wyeth's possession, custody, or control and/or subject to the rights of third parties not affiliated with Wyeth. Wyeth further objects to this request to the extent it seeks documents concerning public meetings at which "an EXTENDED RELEASE FORMULATION comprising microcrystalline cellulose" was "otherwise discussed" as overly broad, unduly burdensome and unreasonable. Wyeth objects to Impax's definition of "named

inventors" to the extent it encompasses persons beyond Deborah M. Sherman, John C. Clark, John U. Lamer and Stephen A. White as vague and ambiguous, overly broad, unduly burdensome, and irrelevant to any issue in the suit. Wyeth further objects to this request to the extent it seeks publicly available documents as unduly burdensome because the burden on Impax is no more than the burden on Wyeth to obtain those documents. To the extent Impax's request would require Wyeth to search through publicly available literature, this request is unduly burdensome and unreasonable. Such printed publications are already available to Impax and Impax can search for such documents on its own.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 55:

All DOCUMENTS and THINGS CONCERNING patents, patent applications, scientific literature, scientific articles, scientific publications, prior knowledge, public uses, sales, offers for sale, or any other prior art publications or activities CONCERNING an EXTENDED RELEASE FORMULATION comprising VENLAFAXINE of which the NAMED INVENTORS or WYETH is aware.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents concerning "EXTENDED RELEASE FORMULATION comprising VENLAFAXINE" which were developed after the effective filing date of the patents in suit other than Effexor® XR as overly broad, unduly burdensome, irrelevant to any issue in the suit, not reasonably

calculated to lead to the discovery of admissible evidence and as seeking highly sensitive future product information. Wyeth further objects to this request to the extent it seeks publicly available patents, patent applications, and publications as unduly burdensome because the burden on Impax is no more than the burden on Wyeth to obtain those documents. To the extent Impax's request would require Wyeth to search through publicly available literature, this request is unduly burdensome and unreasonable. Such printed publications are already available to Impax and Impax can search for such documents on its own. Wyeth objects to Impax's definition of "named inventors" to the extent it encompasses persons beyond Deborah M. Sherman, John C. Clark, John U. Lamer and Stephen A. White as vague and ambiguous, overly broad, unduly burdensome, and irrelevant to any issue in the suit. Wyeth objects to Impax's definition of the terms "Wyeth." This action involves Wyeth and not its past or present, U.S. or foreign subsidiaries, past or present, U.S. or foreign divisions, or "any related companies." In addition, Wyeth objects to Impax's definition of "Wyeth" to the extent these terms include former officers, directors, employees, agents, attorneys or representatives as potentially including entities outside of Wyeth's possession, custody, or control, and as calling for information that may be subject to confidentiality agreements and/or attorney-client privilege. Read literally, it potentially seeks information from countless numbers of Wyeth's employees who are not primarily involved in the issues concerning this case. Consequently, in answering this request, Wyeth will construe "Wyeth" to mean only the named inventors and attorneys involved with the prosecution of the patents-in-suit. Wyeth further objects to this request to the

extent it seeks documents protected by the attorney-client privilege and/or work product immunity.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 56:

ALL DOCUMENTS and THINGS CONCERNING patents, patent applications, scientific literature, scientific articles, scientific publications, prior knowledge, public uses, sales, offers for sale, or any other prior art publications or activities CONCERNING an EXTENDED RELEASE FORMULATION comprising microcrystalline cellulose of which the NAMED INVENTORS or WYETH is aware.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents concerning "an EXTENDED RELEASE FORMULATION comprising microcrystalline cellulose" developed after the effective filing date of the patents in suit as overly broad, unduly burdensome, irrelevant to any issue in the suit, not reasonably calculated to lead to the discovery of admissible evidence and as seeking highly sensitive future product information. Wyeth further objects to this request as literally encompassing formulations that do not even contain venlafaxine. Wyeth further objects to this request to the extent it seeks publicly available patents, patent applications, and publications as unduly burdensome because the burden on Impax is no more than the burden on Wyeth to obtain those documents. To the extent Impax's request would require Wyeth to search through publicly available literature, this request is unduly burdensome and

unreasonable. Such printed publications are already available to Impax and Impax can search for such documents on its own. Wyeth objects to Impax's definition of "named inventors" to the extent it encompasses persons beyond Deborah M. Sherman, John C. Clark, John U. Lamer and Stephen A. White as vague and ambiguous, overly broad, unduly burdensome, and irrelevant to any issue in the suit. Wyeth objects to Impax's definition of the terms "Wyeth." This action involves Wyeth and not its past or present, U.S. or foreign subsidiaries, past or present, U.S. or foreign divisions, or "any related companies." In addition, Wyeth objects to Impax's definition of "Wyeth" to the extent these terms include former officers, directors, employees, agents, attorneys or representatives as potentially including entities outside of Wyeth's possession, custody, or control, and as calling for information that may be subject to confidentiality agreements and/or attorney-client privilege. Read literally, it potentially seeks information from countless numbers of Wyeth's employees who are not primarily involved in the issues concerning this case. Consequently, in answering this request, Wyeth will construe "Wyeth" to mean only the named inventors and attorneys involved with the prosecution of the patents-in-suit. Wyeth further objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 57:

All DOCUMENTS and THINGS CONCERNING the knowledge of the NAMED INVENTORS of U.S. Patent No. 3,954,959 and any patents, patent applications, or patent publications CONCERNING it.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents and things concerning "any patents, patent applications, or patent publications CONCERNING it" as vague and ambiguous, overly broad, unduly burdensome, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth objects to Impax's definition of "named inventors" to the extent it encompasses persons beyond Deborah M. Sherman, John C. Clark, John U. Lamer and Stephen A. White as vague and ambiguous, overly broad, unduly burdensome, and irrelevant to any issue in the suit. Wyeth further objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 58:

All DOCUMENTS and THINGS CONCERNING the knowledge of the NAMED INVENTORS of U.S. Patent No. 4,138,475 or any patents, patent applications, or patent publications CONCERNING it.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents and things concerning "any patents, patent applications, or patent publications CONCERNING it" as vague and ambiguous, overly broad, unduly burdensome, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth objects to Impax's definition of "named inventors" to the extent it encompasses persons beyond Deborah M. Sherman, John C. Clark, John U. Lamer and Stephen A. White as vague and ambiguous, overly broad, unduly burdensome, and irrelevant to any issue in the suit. Wyeth further objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 59:

All DOCUMENTS and THINGS CONCERNING the knowledge of the NAMED INVENTORS of U.S. Patent No. 4,369,172 or any patents, patent applications, or patent publications CONCERNING it.

OBJECTION:

Wyeth objects to this request to the extent it seeks " documents and things concerning "any patents, patent applications, or patent publications CONCERNING it" as vague and ambiguous, overly broad, unduly burdensome, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth objects to

Impax's definition of "named inventors" to the extent it encompasses persons beyond Deborah M. Sherman, John C. Clark, John U. Lamer and Stephen A. White as vague and ambiguous, overly broad, unduly burdensome, and irrelevant to any issue in the suit. Wyeth further objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 60:

All DOCUMENTS and THINGS CONCERNING the knowledge of the NAMED INVENTORS of U.S. Patent No. 4,535,186 or any patents, patent applications, or patent publications CONCERNING it.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents and things concerning "any patents, patent applications, or patent publications CONCERNING it" as vague and ambiguous, overly broad, unduly burdensome, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth objects to Impax's definition of "named inventors" to the extent it encompasses persons beyond Deborah M. Sherman, John C. Clark, John U. Lamer and Stephen A. White as vague and ambiguous, overly broad, unduly burdensome, and irrelevant to any issue in the suit. Wyeth further objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 61:

All DOCUMENTS and THINGS CONCERNING the knowledge of the NAMED INVENTORS of U.S. Patent No. 4,966,768 or any patents, patent applications, or patent publications CONCERNING it.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents and things concerning "any patents, patent applications, or patent publications CONCERNING it" as vague and ambiguous, overly broad, unduly burdensome, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity. Wyeth objects to Impax's definition of "named inventors" to the extent it encompasses persons beyond Deborah M. Sherman, John C. Clark, John U. Lamer and Stephen A. White as vague and ambiguous, overly broad, unduly burdensome, and irrelevant to any issue in the suit.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 62:

All DOCUMENTS and THINGS CONCERNING the knowledge of the NAMED INVENTORS of U.S. Patent No. 5,506,270 or any patents, patent applications, or patent publications CONCERNING it.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents and things concerning "any patents, patent applications, or patent publications CONCERNING it" as vague and ambiguous, overly broad, unduly burdensome, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth objects to Impax's definition of "named inventors" to the extent it encompasses persons beyond Deborah M. Sherman, John C. Clark, John U. Lamer and Stephen A. White as vague and ambiguous, overly broad, unduly burdensome, and irrelevant to any issue in the suit. Wyeth objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 63:

All DOCUMENTS and THINGS CONCERNING the knowledge of the NAMED INVENTORS of U.S. Patent No. 5,552,429 or any patents, patent applications, or patent publications CONCERNING it.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents and things concerning "any patents, patent applications, or patent publications CONCERNING it" as vague and ambiguous, overly broad, unduly burdensome, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth objects to Impax's definition of "named inventors" to the extent it encompasses persons beyond Deborah M. Sherman, John C. Clark, John U. Lamer and Stephen A. White as vague and ambiguous, overly broad, unduly burdensome, and irrelevant to any issue in the suit. Wyeth further objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 64:

All DOCUMENTS and THINGS CONCERNING the knowledge of the NAMED INVENTORS of Publication No. EP0654264 or any patents, patent applications, or patent publications CONCERNING it.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents and things concerning "any patents, patent applications, or patent publications CONCERNING it" as vague and ambiguous, overly broad, unduly burdensome, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth objects to

Impax's definition of "named inventors" to the extent it encompasses persons beyond Deborah M. Sherman, John C. Clark, John U. Lamer and Stephen A. White as vague and ambiguous, overly broad, unduly burdensome, and irrelevant to any issue in the suit. Wyeth further objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 65:

All DOCUMENTS and THINGS CONCERNING the knowledge of the NAMED INVENTORS of Publication No. EP0667150 or any patents, patent applications, or patent publications CONCERNING it.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents and things concerning "any patents, patent applications, or patent publications CONCERNING it" as vague and ambiguous, overly broad, unduly burdensome, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth objects to Impax's definition of "named inventors" to the extent it encompasses persons beyond Deborah M. Sherman, John C. Clark, John U. Lamer and Stephen A. White as vague and ambiguous, overly broad, unduly burdensome, and irrelevant to any issue in the suit. Wyeth further objects to this request to the extent it seeks information protected by the attorney-client privilege and/or work product immunity.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 66:

All DOCUMENTS and THINGS CONCERNING the knowledge of the NAMED INVENTORS of Publication No. EP0797991 or any patents, patent applications, or patent publications CONCERNING it.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents and things concerning "any patents, patent applications, or patent publications CONCERNING it" as vague and ambiguous, overly broad, unduly burdensome, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth objects to Impax's definition of "named inventors" to the extent it encompasses persons beyond Deborah M. Sherman, John C. Clark, John U. Lamer and Stephen A. White as vague and ambiguous, overly broad, unduly burdensome, and irrelevant to any issue in the suit. Wyeth further objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 67:

All DOCUMENTS and THINGS CONCERNING the knowledge of the NAMED INVENTORS of Publication No. WO/1994/027589 or any patents, patent applications, or patent publications CONCERNING it.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents and things concerning "any patents, patent applications, or patent publications CONCERNING it" as vague and ambiguous, overly broad, unduly burdensome, irrelevant, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth objects to Impax's definition of "named inventors" to the extent it encompasses persons beyond Deborah M. Sherman, John C. Clark, John U. Lamer and Stephen A. White as vague and ambiguous, overly broad, unduly burdensome, and irrelevant to any issue in the suit. Wyeth further objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 68:

All DOCUMENTS and THINGS CONCERNING any analysis or discussion of inventorship for the PATENTS IN SUIT or for any non-issued, now abandoned patent applications for which any of the NAMED INVENTORS were at any time listed as an inventor.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity. Wyeth objects to Impax's definition of "named inventors" to the extent it encompasses persons beyond Deborah M. Sherman, John C. Clark, John U. Lamer and Stephen A. White as vague and ambiguous, overly broad, unduly burdensome, and irrelevant to any issue in the suit. Wyeth further objects to this request to the extent it seeks documents concerning inventorship of "any non-issued, now abandoned patent applications for which any of the NAMED INVENTORS were at any time listed as an inventor" as vague and ambiguous, overly broad, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 69:

All DOCUMENTS and THINGS CONCERNING any analysis or discussion of whether the PATENTS IN SUIT are valid, including without limitation opinions, prior art references, and prior art searches.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents that are protected by the attorney-client privilege and/or work product immunity. To the extent that this request seeks the production of internal work product files from any of Wyeth's counsel,

including, but not limited to, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. and Morris, Nichols, Arsht & Tunnell, L.L.P., Wyeth objects to either the production or the listing of these documents on a withheld document list.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 70:

All DOCUMENTS and THINGS that support or contradict an assertion that the claims of the PATENTS IN SUIT are invalid for failing to meet the requirements of 35 U.S.C. sections 101, 102, 103, or 112.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents that are protected by the attorney-client privilege and/or work product immunity. To the extent that this request seeks the production of internal work product files from any of Wyeth's counsel, including, but not limited to, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. and Morris, Nichols, Arsht & Tunnell, L.L.P., Wyeth objects to either the production or the listing of these documents on a withheld document list. Wyeth further objects to this request to the extent it requires Wyeth to review voluminous documents and make a subjective determination of what may or may not "support or contradict" assertions regarding the validity of the claims of the patents in suit. Wyeth also objects to this request to the extent it calls for a legal conclusion in determining the documents that are responsive to the request.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 71:

All DOCUMENTS and THINGS that support or contradict an assertion that the claims of the PATENTS IN SUIT are invalid for non-joinder or mis-joinder in their inventorship group.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents that are protected by the attorney-client privilege and/or work product immunity. To the extent that this request seeks the production of internal work product files from any of Wyeth's counsel, including, but not limited to, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. and Morris, Nichols, Arsht & Tunnell, L.L.P., Wyeth objects to either the production or the listing of these documents on a withheld document list. Wyeth further objects to this request to the extent it requires Wyeth to review voluminous documents and make a subjective determination of what may or may not "support or contradict" any assertion regarding the validity of the claims of the patents in suit. Wyeth also objects to this request to the extent it calls for a legal conclusion in determining the documents that are responsive to the request.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to

document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 72:

All DOCUMENTS and THINGS that support or contradict an assertion that the claims of the PATENTS IN SUIT are invalid for double patenting.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents that are protected by the attorney-client privilege and/or work product immunity. To the extent that this request seeks the production of internal work product files from any of Wyeth's counsel, including, but not limited to, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. and Morris, Nichols, Arsht & Tunnell, L.L.P., Wyeth objects to either the production or the listing of these documents on a withheld document list. Wyeth further objects to this request to the extent it requires Wyeth to review voluminous documents and make a subjective determination of what may or may not "support or contradict" any assertion regarding the validity of the claims of the patents in suit. Wyeth also objects to this request to the extent it calls for a legal conclusion in determining the documents that are responsive to the request.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 73:

All DOCUMENTS and THINGS on which WYETH may rely to establish any secondary considerations of nonobviousness in connection with any of the inventions claimed in the PATENTS IN SUIT.

OBJECTION:

Wyeth objects to this request as premature because, under the Court's Pretrial Scheduling Order, rebuttal expert reports are not due until October 31, 2007.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce the requested documents.

IMPAX DOCUMENT REQUEST NO. 74:

All DOCUMENTS and THINGS CONCERNING nausea, emesis, and any other side effects associated with the administration of immediate release VENLAFAXINE or EFFEXOR.

OBJECTION:

Wyeth objects to the production of voluminous pharmacokinetic trials on immediate release venlafaxine, clinical trials on immediate release venlafaxine and adverse event reports on immediate release venlafaxine as overly broad, unduly burdensome and unreasonably cumulative and duplicative. Wyeth further objects to this request to the extent it seeks documents concerning "any other side effects" as overly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence. The phrase "any other side effects" is without bounds.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to

document requests in the Teva litigation (including the 1993 Pre-approval Safety Update from the originally filed Wyeth NDA for immediate release venlafaxine and the final reports and protocols of the immediate release venlafaxine clinical trials that were reported in that Pre-approval Safety Update) and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 75:

ALL DOCUMENTS and THINGS CONCERNING nausea, emesis, and any other side effects associated with the administration of an EXTENDED RELEASE FORMULATION containing VENLAFAXINE or EFFEXOR XR.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents concerning side effects of any "EXTENDED RELEASE FORMULATION containing VENLAFAXINE" as overly broad, unduly burdensome, irrelevant to any issue in the suit, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to the production of voluminous raw patient data gathered from, for example, pre-clinical studies or clinical trials of Effexor® XR as unduly burdensome and unreasonably cumulative and duplicative. Wyeth further objects to this request to the extent it seeks documents concerning "any other side effects" as overly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 76:

All DOCUMENTS and THINGS sufficient to IDENTIFY profits, sales, advertising expenditures, profit forecasts, sales forecasts, and advertising forecasts CONCERNING any products that embody any claims of the PATENTS IN SUIT or EFFEXOR XR, including without limitation profits, sales, advertising expenditures, profit forecasts, sales forecasts, and advertising forecasts on an annual and monthly basis.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents concerning Plaintiff's products and/or processes outside of the United States as overly broad, irrelevant to any issue in this suit, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it seeks "profits, sales, advertising expenditures, profit forecasts, sales forecasts, and advertising forecasts" as overly broad, irrelevant to any issue in the case and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth also objects to "any products that embody any claims of the PATENTS IN SUIT" as overly broad, vague and ambiguous, not calculated to lead to the discovery of admissible evidence and as potentially seeking information outside of Wyeth's possession, custody or control.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce summary documents reflecting annual sales volume in units and dollars for EFFEXOR® XR in the United States.

IMPAX DOCUMENT REQUEST NO. 77:

All DOCUMENTS and THINGS sufficient to IDENTIFY profits, sales, advertising expenditures, profit forecasts, sales forecasts, and advertising forecasts CONCERNING

EFFEXOR, including without limitation profits, sales, advertising expenditures, profit forecasts, sales forecasts, and advertising forecasts on an annual and monthly basis.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents concerning Plaintiff's products and/or processes outside of the United States as overly broad, irrelevant to any issue in this suit, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it seeks "profits, sales, advertising expenditures, profit forecasts, sales forecasts, and advertising forecasts" as overly broad, irrelevant to any issue in the case and not reasonably calculated to lead to the discovery of admissible evidence.

RESPONSE:

Subject to the General and Specific Objections, Wyeth produce summary documents reflecting annual sales volume in units and dollars for EFFEXOR® in the United States.

IMPAX DOCUMENT REQUEST NO. 78:

All DOCUMENTS and THINGS CONCERNING any WYETH policy, strategy, plan, or practice, whether formal or informal, stated or unstated, regarding patents, including but not limited to filing patent applications, acquiring patents or patent applications from other persons, exploiting patents or patented technology, charging other persons with patent infringement, enforcing patents, licensing patents or patented technology, or cross-licensing patents or patented technology.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request to the extent it seeks documents and things concerning "any WYETH policy,

strategy, plan, or practice, whether formal or informal, stated or unstated regarding patents" as overly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it calls for documents generated subsequent to February 10, 2003. To the extent this request seeks production of internal work product files from any of Wyeth's counsel including, but not limited to, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. and Morris, Nichols, Arsht & Tunnell, LLP, Wyeth objects to either the production or listing of these documents on a withheld document list. Wyeth further objects to this request to the extent it seeks documents and things concerning any "WYETH policy, strategy, plan, or practice" other than any regarding "charging other persons with patent infringement" or "enforcing patents," as overly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence.

RESPONSE:

Subject to the General and Specific Objections and to the extent it understands this request, Wyeth will identify protected documents on a withheld document list and will produce the requested documents to the extent they are not protected by the attorney-client privilege and/or work product immunity.

IMPAX DOCUMENT REQUEST NO. 79:

ALL DOCUMENTS and THINGS CONCERNING the need, desirability, or consideration of filing continuation-in-part applications, divisional applications, or continuation applications claiming priority in the PATENTS IN SUIT.

OBJECTION and RESPONSE:

Wyeth objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request to the extent it seeks documents and things concerning "the need, desirability, or consideration of filing" the applications recited as overly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it calls for documents generated subsequent to February 10, 2003. To the extent this request seeks production of internal work product files from any of Wyeth's counsel including, but not limited to, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. and Morris, Nichols, Arsht & Tunnell, LLP, Wyeth objects to either the production or listing of these documents on a withheld document list.

IMPAX DOCUMENT REQUEST NO. 80:

ALL DOCUMENTS AND THINGS CONCERNING the need, desirability, consideration of any application for reissue or request for reexamination of the **PATENTS IN SUIT.**

OBJECTION and RESPONSE:

Wyeth objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request to the extent it seeks documents and things concerning "the need, desirability, or consideration of any application" for reissue or reexamination as overly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further

objects to this request to the extent it calls for documents generated subsequent to February 10, 2003. To the extent this request seeks production of internal work product files from any of Wyeth's outside counsel including, but not limited to, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. and Morris, Nichols, Arsht & Tunnell, LLP, Wyeth objects to either the production or listing of these documents on a withheld document list.

IMPAX DOCUMENT REQUEST NO. 81:

All DOCUMENTS and THINGS CONCERNING the need, desirability, consideration of any foreign patent application (including any application or request for reexamination or reissue of any foreign patent) in connection with any alleged invention covered by any claim of the PATENTS IN SUIT.

OBJECTION and RESPONSE:

Wyeth objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity. Wyeth further objects to this request to the extent it seeks documents and things concerning "any foreign patent application" as overly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence.

IMPAX DOCUMENT REQUEST NO. 82:

All DOCUMENTS and THINGS CONCERNING WYETH's document retention or document destruction policy, including but not limited to, all preservation memoranda or standard operating procedures relating to the PATENTS IN SUIT, EFFEXOR, EFFEXOR XR, or the above-captioned action.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents and things concerning Wyeth's document retention or document destruction policy (without limitation as to either subject matter or time) as overly broad, vague and ambiguous, unduly burdensome, irrelevant to any issue in this litigation, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it seeks documents protected by the attorney-client privilege and/or work product immunity.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will identify protected documents on a withheld document list and will produce the requested documents to the extent they are not protected by the attorney-client privilege and/or work product immunity.

IMPAX DOCUMENT REQUEST NO. 83:

All organizational charts of WYETH that list or include the NAMED INVENTORS.

OBJECTION:

Wyeth objects to Impax's definition of "named inventors" to the extent it encompasses persons beyond Deborah M. Sherman, John C. Clark, John U. Lamer and Stephen A. White as vague and ambiguous, overly broad, unduly burdensome, and irrelevant to any issue in the suit.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to

document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 84:

All organizational charts of WYETH CONCERNING research, development, manufacturing, testing, production, assembly, distribution, sales, marketing, regulatory approval of EFFEXOR or EFFEXOR XR.

OBJECTION:

Wyeth objects to this request as overly broad, vague and ambiguous, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it seeks organizational charts concerning, for example, routine manufacturing, testing, production, distribution, and assembly organizations, processes, and procedures as overly broad, irrelevant to any issue in this litigation, and as not calculated to lead to the discovery of admissible evidence.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 85:

WYETH's annual reports to shareholders, annual and quarterly profit and loss statements, Form 10-K reports to the U.S. Securities and Exchange Commission, and any prospectus prepared or filed that CONCERNS EFFEXOR or EFFEXOR XR.

OBJECTION:

Wyeth objects to this request to the extent it seeks documents concerning "any prospectus prepared or filed that CONCERNS EFFEXOR or EFFEXOR XR" as unduly burdensome, overly broad, vague and ambiguous, irrelevant to any issue in this suit, and not reasonably calculated to lead to the discovery of admissible evidence. Wyeth further objects to this request to the extent it seeks production of documents available in the public domain as unduly burdensome to collect, this burden falling equally on the requesting party. To the extent Impax's request would require Wyeth to search through publicly available literature, this request is unduly burdensome and unreasonable. Such printed publications are already available to Impax and Impax can search for such documents on its own.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

IMPAX DOCUMENT REQUEST NO. 86:

All DOCUMENTS and THINGS CONCERNING IMS data, Medco data, Scott-Levin audit data, or other data from third-party providers CONCERNING sales, prescriptions, or costs of EFFEXOR or EFFEXOR XR.

OBJECTION:

Wyeth objects to this request to the extent it seeks production of documents available in the public domain as unduly burdensome to collect, this burden falling

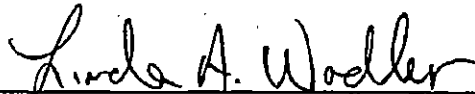
equally on the requesting party. To the extent Impax's request would require Wyeth to search through publicly available literature, this request is unduly burdensome and unreasonable. Such printed publications are already available to Impax and Impax can search for such documents on its own. Wyeth further objects to this request to the extent it seeks documents and things not within Wyeth's possession, custody, or control and/or subject to the rights of third parties not affiliated with Wyeth.

RESPONSE:

Subject to the General and Specific Objections, Wyeth will produce non-privileged documents and things previously produced by Wyeth in response to document requests in the Teva litigation and will identify protected documents associated with that production on a withheld document log.

Dated: July 31, 2006

By:



Basil J. Lewis, Esq.
Linda A. Wadler, Esq.
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Attorneys for Plaintiff Wyeth

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AUG - 1 2006

RICHARD K. HERRMANN

CERTIFICATE OF SERVICE

I, Linda A. Wadler, hereby certify that on the 31st day of July, 2006, I caused true and correct copies of WYETH'S RESPONSES TO DEFENDANT IMPAX'S FIRST SET OF INTERROGATORIES (NOS. 1-19) and PLAINTIFF'S RESPONSES AND OBJECTIONS TO IMPAX'S SECOND REQUEST FOR PRODUCTION OF DOCUMENTS AND THINGS (Nos. 5-86) to be served by FedEx overnight delivery upon the following:

Attorneys for IMPAX LABORATORIES, INC.

Mary B. Matterer
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Jessica R. Wolff
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Dated: July 31, 2006
Washington, D.C.

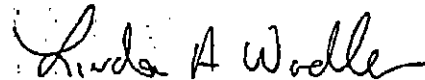

Linda A. Wadler

EXHIBIT 9

AUG 03 2006 17:55 FR FINNEGAN HENDERSON 202 408 4400 TO 14157726268#

P.01

LAW OFFICES
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FACSIMILE TRANSMITTAL

<u>TO</u>	<u>FROM</u>
Name: Daniel N. Kassabian, Esq.	Name: Linda A. Wadler, Esq.
Firm: Heller Ehrman LLP	Phone No.: (202) 408-4037
Fax No.: 415-772-6268	Fax # Verified by: A. Norris - MD 8113
Phone No.: 415-772-6098	# Pages (Incl. this): 5
Subject: Wyeth v. Impax	Date: August 3, 2006

Our File No.:

Confirmation Copy to Follow: NO

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August 3, 2006

Daniel N. Kassabian, Esq.
Heller Ehrman LLP
333 Bush Street
San Francisco, CA 94104

Via Facsimile

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 (D. Del.)

Dear Daniel:

I am writing in response to your letter of July 31, 2006 regarding Wyeth's Responses and Objections to Impax's First Request for Production of Documents and Things (Nos. 1-4).

With respect to General Objection No. 5, Wyeth has indicated that it will provide information available from a reasonable search of its own files at its principal offices and pharmaceutical product research and development facilities in the United States. Your insistence that Wyeth greatly expand this search to encompass "foreign locations and/or foreign affiliates" is overly broad, irrelevant, unreasonably cumulative, unduly burdensome and not reasonably calculated to lead to discoverable evidence. Wyeth has already agreed to produce over 1.3 million pages from its principal U.S. facilities in response to Impax's first of 86 document requests. It would be unduly burdensome to extend this search to the more than 80 foreign countries in which Wyeth maintains one or more business facilities. Such discovery would be largely irrelevant, and indeed largely duplicative of that undertaken in the United States.

Not surprisingly, Impax has not articulated why it needs discovery from Wyeth's foreign locations and/or foreign affiliates. Although Impax notes that Study 600B-367-EU took place in Europe, Impax ignores the fact that this same study was submitted to the U.S. FDA in connection with NDA 20-699, Wyeth's NDA for Effexor® XR. Consequently, the relevant documents relating to Study 600B-367-EU are available in the United States in connection with NDA 20-699. Impax has not established either the relevance of foreign discovery or any need that would outweigh the enormous burden of collecting and producing such documents.

AUG 03 2006 17:55 FR FINNEGAN HENDERSON 202 408 4400 TO 14157726268#

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Daniel N. Kassabian, Esq.
August 3, 2006
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Moreover, the cases Impax cites do not compel world-wide discovery of Wyeth facilities. In *Avery Dennison Corp. v. UCB Films PLC*, No. 95-6351, 1998 WL 293002 (N.D. Ill. May 28, 1998), the court compelled production of documents from two of Avery Dennison's out of state agents—a far less onerous production than the extensive international discovery that Impax demands here. In *Manville Sales Corp. v. Paramount Sys., Inc.*, No. 86-4157, 1987 WL 14794, (E.D. Pa. Oct. 20, 1987), by contrast, the court compelled production of specific interrogatory responses relating to relatively limited areas of sales, competitors and agreements outside of the United States. *Manville Sales* does not support the proposition that foreign document collection and production is required for every single request, let alone from the more than 60 countries in which Wyeth maintains one or more business facilities. To the contrary, *Manville Sales* emphasizes that “the District Court should not neglect their power to restrict discovery where justice requires (protection for) a party . . . (from) oppression or undue burden or expense.” *Id.* at *2 (citing *Herbert v. Lando*, 441 U.S. 153 (1979)).

With respect to Wyeth's General Objection No. 10 and without waiving any objection to the production of documents and things protected by any other applicable privilege (see General Objection No. 2) we confirm that General Objection No. 10 indicates that we will not list privileged communications with Wyeth occurring after February 10, 2003 relating to litigation concerning the subject matter of the patents in suit or internal attorney work product files from Wyeth's counsel. Your implication that Wyeth “will not provide a withheld document list” with respect to other categories of documents is not well taken. General Objection No. 2, for example, asserts on its face that a listing of withheld documents “will be prepared in due course and exchanged with Impax on a mutually agreed upon date.”

With respect to the scope of documents that must be included on a withheld document list, we understand and accept that Impax is willing to exclude attorney work product generated after April 5, 2006 in the course of litigation from either party's withheld document log. We do not agree, however, to list the voluminous attorney work product generated in connection with the Teva litigation or any other lawsuit relating to Effexor[®] XR for the same reason that Impax is willing to make the above stipulation. Namely, that the listing of such protected materials is unduly burdensome and unnecessary.

Turning now to General Objection No. 11, with respect to Wyeth's objections to the production of non-Wyeth documents or information subject to a protective order entered in any other litigation, you assert that that “Impax is not seeking Teva's confidential information,” although Impax nonetheless seeks information “that may be considered jointly confidential by Wyeth and Teva.” We fail to see how the confidentiality of Teva's information depends on whether Wyeth believes that it is

AUG 03 2006 17:56 FR FINNEGAN HENDERSON 202 408 4400 TO 14157726268H

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Daniel N. Kassabian, Esq.
August 3, 2006
Page 3

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also confidential to Wyeth. You further acknowledge the difficulty of identifying with particularity the information—whether of Wyeth or Teva—deemed by Teva to be confidential.

With respect to your request that we provide Impax with a "listing / docket of all pleadings (including briefing filed under seal or lodged with the Court), all depositions, and all hearings and conferences," we note that this information is publicly available from the Court's docket. Thus, it would simply be more efficient for Impax to obtain it directly, rather than for Wyeth to obtain it and subsequently forward it to you.

With respect to your discussion of General Objection No. 13 concerning the costs of producing documents in this litigation, Impax has already requested the production of over 1.3 million pages. With respect to the documents previously produced in the Teva litigation, Impax should not receive a windfall by receiving images of documents produced in a prior litigation free of cost. Thus, rather than bear the lion's share of costs, Wyeth has proposed that Impax reimburse Wyeth for half the cost of imaging the documents it has requested from Wyeth's production in the Teva litigation (half of 12 cents per page), or the full cost of producing paper copies (6 cents per page). This proposal seems more than reasonable as Impax can still enjoy the benefit of obtaining imaged documents at half price.

Impax has indicated that it would provide Wyeth with an estimate of the number of pages it expects to produce in this litigation. Please provide us with that estimate, as well as your imaging and copy costs on a per page basis, as soon as possible. Once we receive that estimate, we will be in a better position to discuss with you the proportionate costs of each other's production. Further in response to your discussion of General Objection No. 13, we ask you to cite any authority for your argument that the new discovery rules—which will not come into effect until the productions here are scheduled to have been completed—somehow requires that a party provide electronic coding created not in the ordinary course of business, but in litigation.

Finally, with respect to your concern regarding General Objection No. 14 and the production of documents or information generated subsequent to the February 10, 2003 cut-off date observed in the Teva litigation, we note that the patents in suit were filed in 1996 and issued in either 2001 or 2002. Subsequently created Wyeth documents are thus largely irrelevant and Impax has not articulated any reason for a broad collection and production of all requested documents created after the February 10, 2003 cut-off date. In addition, the document collection that has already been done was generated from interviews with over 200 people and resulted in the production of over 1 million pages. The amount of time and additional cost required to perform a broad update of this collection in the U.S. alone would be enormous,

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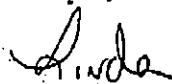
Daniel N. Kassabian, Esq.
August 3, 2006
Page 4

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particularly when weighed against the likelihood of finding relevant material. Wyeth further notes that, without waiving our general objection to producing documents created after the cut-off date, Wyeth has agreed to produce selected categories of relevant documents created after February 10, 2003 in response to at least Impax's Document Request Nos. 2 through 4 as well as additional document requests contained in Impax's second set of document requests.

We look forward to your receiving your response to the points raised in this letter in the near future.

Sincerely,



Linda A. Wadler

LAW/RAP/amn

cc: Mary B. Matterer, Esq. (via Facsimile)
Richard K. Herrmann, Esq. (via Facsimile)

1152293-1

EXHIBIT 10

**EXHIBIT REDACTED
IN ITS ENTIRETY**

EXHIBIT 11

**EXHIBIT REDACTED
IN ITS ENTIRETY**

EXHIBIT 12

AUG 03 2006 17:55 FR FINNEGAN HENDERSON 202 408 4400 TO 14157726268#

P.01

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FACSIMILE TRANSMITTAL

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Name: Daniel N. Kassabian, Esq.	Name: Linda A. Wadler, Esq.
Firm: Heller Ehrman LLP	Phone No.: (202) 408-4037
Fax No.: 415-772-6268	Fax # Verified by: A. Norris - MD 8113
Phone No.: 415-772-6098	# Pages (Incl. this): 5
Subject: Wyeth v. Impax	Date: August 3, 2006

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LINDA A. WADLER
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August 3, 2006

Daniel N. Kassabian, Esq.
Heller Ehrman LLP
333 Bush Street
San Francisco, CA 94104

Via Facsimile

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 (D. Del.)

Dear Daniel:

I am writing in response to your letter of July 31, 2006 regarding Wyeth's Responses and Objections to Impax's First Request for Production of Documents and Things (Nos. 1-4).

With respect to General Objection No. 5, Wyeth has indicated that it will provide information available from a reasonable search of its own files at its principal offices and pharmaceutical product research and development facilities in the United States. Your insistence that Wyeth greatly expand this search to encompass "foreign locations and/or foreign affiliates" is overly broad, irrelevant, unreasonably cumulative, unduly burdensome and not reasonably calculated to lead to discoverable evidence. Wyeth has already agreed to produce over 1.3 million pages from its principal U.S. facilities in response to Impax's first of 86 document requests. It would be unduly burdensome to extend this search to the more than 80 foreign countries in which Wyeth maintains one or more business facilities. Such discovery would be largely irrelevant, and indeed largely duplicative of that undertaken in the United States.

Not surprisingly, Impax has not articulated why it needs discovery from Wyeth's foreign locations and/or foreign affiliates. Although Impax notes that Study 600B-367-EU took place in Europe, Impax ignores the fact that this same study was submitted to the U.S. FDA in connection with NDA 20-699, Wyeth's NDA for Effexor[®] XR. Consequently, the relevant documents relating to Study 600B-367-EU are available in the United States in connection with NDA 20-699. Impax has not established either the relevance of foreign discovery or any need that would outweigh the enormous burden of collecting and producing such documents.

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Daniel N. Kassabian, Esq.
 August 3, 2006
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Moreover, the cases Impax cites do not compel world-wide discovery of Wyeth facilities. In *Avery Dennison Corp. v. UCB Films PLC*, No. 95-6351, 1998 WL 293002 (N.D. Ill. May 28, 1998), the court compelled production of documents from two of Avery Dennison's out of state agents—a far less onerous production than the extensive international discovery that Impax demands here. In *Manville Sales Corp. v. Paramount Sys., Inc.*, No. 86-4157, 1987 WL 14794, (E.D. Pa. Oct. 20, 1987), by contrast, the court compelled production of specific interrogatory responses relating to relatively limited areas of sales, competitors and agreements outside of the United States. *Manville Sales* does not support the proposition that foreign document collection and production is required for every single request, let alone from the more than 60 countries in which Wyeth maintains one or more business facilities. To the contrary, *Manville Sales* emphasizes that “the District Court should not neglect their power to restrict discovery where justice requires (protection for) a party . . . (from) oppression or undue burden or expense.” *Id.* at *2 (citing *Herbert v. Lando*, 441 U.S. 153 (1979)).

With respect to Wyeth's General Objection No. 10 and without waiving any objection to the production of documents and things protected by any other applicable privilege (*see* General Objection No. 2) we confirm that General Objection No. 10 indicates that we will not list privileged communications with Wyeth occurring after February 10, 2003 relating to litigation concerning the subject matter of the patents in suit or internal attorney work product files from Wyeth's counsel. Your implication that Wyeth “will not provide a withheld document list” with respect to other categories of documents is not well taken. General Objection No. 2, for example, asserts on its face that a listing of withheld documents “will be prepared in due course and exchanged with Impax on a mutually agreed upon date.”

With respect to the scope of documents that must be included on a withheld document list, we understand and accept that Impax is willing to exclude attorney work product generated after April 5, 2006 in the course of litigation from either party's withheld document log. We do not agree, however, to list the voluminous attorney work product generated in connection with the Teva litigation or any other lawsuit relating to Effexor[®] XR for the same reason that Impax is willing to make the above stipulation. Namely, that the listing of such protected materials is unduly burdensome and unnecessary.

Turning now to General Objection No. 11, with respect to Wyeth's objections to the production of non-Wyeth documents or information subject to a protective order entered in any other litigation, you assert that that “Impax is not seeking Teva's confidential information,” although Impax nonetheless seeks information “that may be considered jointly confidential by Wyeth and Teva.” We fail to see how the confidentiality of Teva's information depends on whether Wyeth believes that it is

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P.04

Daniel N. Kassabian, Esq.
August 3, 2006
Page 3

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With respect to your request that we provide Impax with a "listing / docket of all pleadings (including briefing filed under seal or lodged with the Court), all depositions, and all hearings and conferences," we note that this information is publicly available from the Court's docket. Thus, it would simply be more efficient for Impax to obtain it directly, rather than for Wyeth to obtain it and subsequently forward it to you.

With respect to your discussion of General Objection No. 13 concerning the costs of producing documents in this litigation, Impax has already requested the production of over 1.3 million pages. With respect to the documents previously produced in the Teva litigation, Impax should not receive a windfall by receiving images of documents produced in a prior litigation free of cost. Thus, rather than bear the lion's share of costs, Wyeth has proposed that Impax reimburse Wyeth for half the cost of imaging the documents it has requested from Wyeth's production in the Teva litigation (half of 12 cents per page), or the full cost of producing paper copies (6 cents per page). This proposal seems more than reasonable as Impax can still enjoy the benefit of obtaining imaged documents at half price.

Impax has indicated that it would provide Wyeth with an estimate of the number of pages it expects to produce in this litigation. Please provide us with that estimate, as well as your imaging and copy costs on a per page basis, as soon as possible. Once we receive that estimate, we will be in a better position to discuss with you the proportionate costs of each other's production. Further in response to your discussion of General Objection No. 13, we ask you to cite any authority for your argument that the new discovery rules—which will not come into effect until the productions here are scheduled to have been completed—somehow requires that a party provide electronic coding created not in the ordinary course of business, but in litigation.

Finally, with respect to your concern regarding General Objection No. 14 and the production of documents or information generated subsequent to the February 10, 2003 cut-off date observed in the Teva litigation, we note that the patents in suit were filed in 1996 and issued in either 2001 or 2002. Subsequently created Wyeth documents are thus largely irrelevant and Impax has not articulated any reason for a broad collection and production of all requested documents created after the February 10, 2003 cut-off date. In addition, the document collection that has already been done was generated from interviews with over 200 people and resulted in the production of over 1 million pages. The amount of time and additional cost required to perform a broad update of this collection in the U.S. alone would be enormous,

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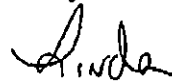
Daniel N. Kassabian, Esq.
August 3, 2006
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We look forward to your receiving your response to the points raised in this letter in the near future.

Sincerely,



Linda A. Wadler

LAW/RAP/amn

cc: Mary B. Matterer, Esq. (via Facsimile)
Richard K. Herrmann, Esq. (via Facsimile)

1162293-1

EXHIBIT 13

HellerEhrman LLP

July 31, 2006

Via E-mail and U.S. Mail

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Main +1.415.772.6000
Fax +1.415.772.6268

40443.0005

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Garrett & Dunner LLP
901 New York Avenue, NW
Washington, D.C. 20001-4413

Re: Wyeth v. Impax Laboratories, Inc.
U.S. District Court, District of Delaware, Civil Action No. 06-222 JJF

Dear Linda:

Following up on my letter dated July 24, 2006, and my e-mail on the same day requesting counsel to meet and confer last week, I write again to seek a time for counsel to meet and confer regarding electronic discovery. Beyond the issues raised in my July 24th letter, we also wish to meet and confer regarding the objections raised in Plaintiff's Responses and Objections to Impax's First Request for Production of Documents and Things (Nos. 1-4) (hereinafter "Plaintiff's Responses") discussed below.

In its general objection no. 5, Wyeth indicates that it will restrict its searching for relevant files to "its principal offices and pharmaceutical product research and development facilities in the United States" Pl.'s Resps., at 2; *see also id.* at 4 (general objection no. 12 states: "'Wyeth' to mean only those portions of Wyeth involved with . . . the venlafaxine hydrochloride extended release product EFFEXOR® XR in the United States."). Such a geographical limitation is wholly improper. First, one of the relevant clinical studies, namely 600B-367-EU, took place in Europe and, combining this fact with Wyeth's global presence, it is likely that Wyeth's foreign locations and/or foreign affiliates have relevant documents in their possession. When relevant documents and things are sought from a party in discovery, the responding party's obligations to produce extend to all documents and things in its possession, custody, and control, not just those located within the United States. *See, e.g., Avery Dennison Corp. v. UCB Films PLC*, No. 95-6351, 1998 WL 293002, at *1 (N.D. Ill. May 28, 1998) ("Federal district courts have ordered parties to demand release of their records from others maintaining custody of those records, regardless of where the documents were located, so that the parties could comply with federal civil discovery requests."); *Manville Sales Corp. v. Paramount Sys., Inc.*, No. 86-4157, 1987 WL 14794, *3 (E.D. Pa.

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			Silicon Valley	Singapore	Washington, D.C.			

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Linda A. Wadler, Esq.
July 31, 2006
Page 2

Oct. 20, 1987) ("this Court finds that information regarding the product and documents concerning information and activities outside the United States and Canada can lead to admissible evidence and shall be supplied."). Accordingly, Impax demands that Wyeth produce all non-privileged and responsive documents and things regardless of their location within or outside the United States.

In its general objection no. 10, Wyeth objects to producing or listing (on a withheld document list / privilege log) any internal work-product files from any of Wyeth's counsel. See Pl.'s Resp., at 3. First, please confirm that this objection is referring only to documents and things that fall within the attorney work-product doctrine set forth in Federal Rule of Civil Procedure 26(b)(3) & (4) or are privileged attorney-client communications, and not some broader category of documents that are not protected or initially immune from discovery. Second, Wyeth's objection that it will not provide a withheld document list is in contravention of Rule 26(b)(5). Impax is willing to stipulate to not exchanging such withheld document lists (or privilege logs) with respect to attorney-work product in this litigation (i.e., work-product subsequent to the filing of the complaint), but will not agree to Wyeth unilaterally withholding, without a list or log indicating as to what exactly is being withheld, attorney work-product files that are responsive to Impax's requests and that were generated prior to the filing of the complaint in this action.

In its general objection no. 11, Wyeth "objects to the production of non-Wyeth documents or information subject to a protective order entered in litigation other than the above-captioned litigation." Pl.'s Resp., at 4. Moreover, in specific objections set forth in responses to document request nos. 3 and 4, Wyeth objects to producing certain pleadings, transcripts, and exhibits from *Wyeth v. Teva Pharmaceuticals USA, Inc. et al.*, Civil Action No. 03-CV-1293 (WJM) ("the Teva litigation"), stating:

The Teva litigation involved a different Party and product, and information regarding that Party and product, is simply not relevant to this present litigation. Furthermore, Teva has designated the bulk of this information as confidential and subject to the protective order in place in the Teva litigation, and it would be unduly burdensome to attempt to redact this information. Moreover, under the protective order in that litigation, Teva, not Wyeth, would have to redact information it designated as confidential.

Pl.'s Resp., at 9. First, Impax is not seeking Teva's confidential information, such as Teva's confidential product information. At most it seeks information that only Wyeth considers confidential or that may be considered jointly confidential by Wyeth and Teva, such as the settlement agreement and settlement negotiations in the Teva litigation. Second, Impax does not see a basis in the protective order entered in the Teva litigation, or otherwise, for Wyeth's assertion that Teva must redact the information it considers confidential from documents in

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Linda A. Wadler, Esq.
July 31, 2006
Page 3

Wyeth's possession. At most, Teva may be required to designate with particularity its confidential information (to the extent it already has not done so pursuant to the protective order) so that Wyeth can redact accordingly any responsive document that is to be produced to Impax. Because this issue requires Teva's input, counsel for Impax will send a letter to Teva, its counsel from the Teva litigation, and Wyeth, requesting that Teva designate specific pleadings, transcripts, exhibits or portions thereof as confidential. Wyeth can then produce any pleadings not so designated, and the parties can agree upon a redaction protocol for the remainder. In the spirit of cooperation and eliminating the guess-work in such a process, we ask that Wyeth provide Impax a listing / docket of all pleadings (including briefing filed under seal or lodged with the court), all depositions, and all hearings and conferences. By examining such a listing / docket, Impax can further delineate the specific pleadings, transcripts, and exhibits it seeks because they are relevant to this litigation, and avoid production by Wyeth or Teva of irrelevant documents.

In its general objection no. 13, Wyeth objects to the production of electronic documents. Wyeth also restates the position it has taken in previous meet and confer discussions that it will produce documents in TIFF format if Impax agrees to the same and further agrees to reimburse Wyeth "for half of the cost of imaging copies of documents previously imaged for the Teva litigation and for the full cost of imaging copies of any documents produced solely in this litigation." Pl.'s Resps., at 5. Alternatively, Wyeth is willing to produce in paper format with Impax reimbursing Wyeth for the full cost of such productions. *See id.* First, Impax continues to disagree with Wyeth's view that a production in TIFF format is sufficient for electronic documents, especially in light of the new amendments to the discovery rules that will take effect during the course of this litigation. Second, as previously set forth in my July 24th letter, Impax requests authority for Wyeth's assertion that Impax must bear Wyeth's costs of production. This is especially questionable with respect to documents collected and imaged during a prior litigation. It appears that the majority of the associated imaging costs was incurred before this litigation commenced, and thus would not result from Impax's request for copies of the same. Third, in order to achieve more clarity on Wyeth's proposal, Impax further requests specifics as to the dollar amounts that Wyeth seeks in reimbursement for producing TIFF files, or paper copies, of the documents produced in the Teva litigation. Finally, we need to discuss more concretely what costs Wyeth is preparing to bear in connection with the production of documents from Impax.

In its general objection no. 14, Wyeth objects to producing "documents generated subsequent to the February 10, 2003 cut-off date observed in the Teva litigation" or a withheld document log for such documents. Pl.'s Resps., at 5. Not only is a previously observed cut-off date in another matter not binding on Impax, but Wyeth has not articulated compelling reasons why such a cut-off is appropriate in this case. Per my July 24th letter, the parties have agreed to further meet and confer on this issue and we ask that you do so promptly. In any case, because Impax's request nos. 3 and 4 seek documents that post-date

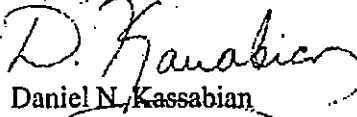
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Linda A. Wadler, Esq.
July 31, 2006
Page 4

this cut-off and that are highly relevant, Impax requests confirmation that this cut-off date is not a basis by which Wyeth will withhold or delay the production of the pleadings, transcripts, and exhibits in the Teva litigation sought in these requests.

Finally, I note that Impax needs to receive and review responsive documents produced by Wyeth sufficiently in advance of the Court's deadline to amend the pleadings, currently set for August 10th, and of the Court's deadline for responses to contention interrogatories, currently set for October 10th. Consequently, we would appreciate a further meet and confer this week in an attempt to resolve the questions, issues, and proposals raised above and in my July 24th letter. We are available the late morning or early afternoon on August 2nd or August 4th. If the parties cannot come to an agreement on these issues, Impax will be forced to seek the Court's intervention by way of motion to compel, which it will file no later than August 10th.

Best regards,


Daniel N. Kassabian

cc: M. Patricia Thayer, Esq.
Jessica R. Wolff, Esq.
Samuel F. Ernst, Esq.
Richard K. Hermann, Esq.
Mary B. Matterer, Esq.
Jack B. Blumenfeld, Esq.
Karen Jacobs Loudon, Esq.

EXHIBIT 14

07/26/2006 14:52 2024084400

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PAGE 01

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<u>TO</u>	<u>FROM</u>
Name: Jessica R. Wolff, Esq. Daniel N. Kassabian, Esq.	Name: Linda A. Wadler, Esq.
Firm: Heller Ehrman LLP	Phone No.: (202) 408-4037
Fax No.: 858-450-8499	Fax # Verified by: A. Norris - MD 8113
Phone No.: 858-450-8400	# Pages (incl this): 2
Subject: Wyeth v. Impax	Date: July 26, 2006

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LINDA A. WADLER
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July 26, 2006

Jessica R. Wolff, Esq.
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4350 La Jolla Village Drive, 7th Floor
San Diego, CA 92101

Via Facsimile

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 JJF (D. Del.)

Dear Jessica:

I am writing in response to your proposals regarding modification of the Scheduling Order in this case. You first proposed that the present August 10, 2006 date for amendment of pleadings be moved back to the March 30, 2007 date for joinder of other parties. In addition, you proposed that a fact discovery cut off date be set in July 2007 and that that same date would also be a final deadline to update contention interrogatory answers.

The Court entered the current Scheduling Order after considering the competing proposals of the parties. We see no need for modification of Judge Faman's schedule and believe that the Scheduling Order reflects the Court's views as to how the case should be managed.

Sincerely,

Handwritten signature of Linda A. Wadler in cursive script.
Linda A. Wadler

LAW/amn

cc: Mary B. Matterer, Esq. (via facsimile)
Richard K. Herrmann, Esq. (via facsimile)

Washington, DC • Atlanta, GA • Cambridge, MA • Palo Alto, CA • Reston, VA • Brussels • Taipei • Tokyo

EXHIBIT 15

08/02/2006 16:17 2024084400

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PAGE 01/03

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Washington, DC 20001

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<u>TO</u>	<u>FROM</u>
Name: Samuel Ernst, Esq.	Name: Linda A. Wadler, Esq.
Firm: Heller Ehrman LLP	Phone No.: (202) 408-4037
Fax No.: 415-772-6268	Fax # Verified by: A. Norris - MD 8113
Phone No.: 415-772-6000	# Pages (incl. this): 3
Subject: Wyeth v. Impax	Date: August 2, 2006

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August 2, 2006

Samuel F. Ernst, Esq.
Heller Ehrman LLP
333 Bush Street
San Francisco, CA 94140-2878

Via Facsimile

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 (D. Del.)

Dear Samuel:

I am writing in response to your letter of July 31, 2006 requesting production of certain documents by Friday, August 4th. Given the large number of documents involved (over 86,000 pages), your request for production in less than one week is not reasonable.

Specifically, Wyeth's objections and responses to the majority of Impax's document requests were due on the very day you wrote your letter -- July 31st. The Court's schedule, moreover, does not envision document production to be completed until October 10, 2006, notwithstanding the earlier date for amendment of pleadings. Impax itself has yet to produce a single document in response to Wyeth's document requests. Finally, the Court's Scheduling Order issued on July 13, 2006. If Impax felt that they needed particular documents on an expedited basis in connection with the amendment of pleadings deadline, it should have requested them earlier. Instead, Impax has waited almost three weeks to send a letter after the close of business on July 31st requesting production of tens of thousands of pages of documents in three business days. Your threat to file a motion to compel at this juncture is disturbing and entirely inappropriate.

We will accept your offer to pay for paper copies for production documents from Wyeth's NDA No. 20-699 and deposition transcripts of the named inventors, Dr. Mangano, and Mr. Alaburda and will begin processing those documents for production to you in the near future.¹ This acceptance is made without prejudice to our right to

¹ In light of Impax counsel's August 1, 2006 letter to Teva Counsel, Henry Dinger, asking whether the deposition transcripts of the named inventors, Dr. Mangano and Mr. Alaburda contain Teva confidential information, we will wait to hear Teva's response before production of those deposition transcripts.

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PAGE 03/03

Samuel F. Ernst, Esq.
August 2, 2006
Page 2

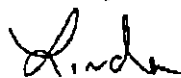
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HENDERSON
FARABOW
GARRETT &
DUNNER

assert in the future that we will not later produce the same documents to you in TIFF format.

With respect to your request for the "Proposed Amended Complaint submitted...on or around April 1, 2005 as Exhibit D to a declaration of Lana Shvartsman," no such document exists. Exhibit D is a copy of a case. Although a proposed amended answer does exist, it was filed under seal subject to the protective order in that litigation by Teva. As a result, we cannot provide you with such information without getting approval from Teva. It is not reasonable to approach Teva in a piecemeal fashion with requests for de-designation of documents they have marked as subject to the protective order in the previous litigation. We need a more comprehensive way of addressing any production of documents subject to third party confidentiality.

Finally, it remains Wyeth's position that the Court entered the current Scheduling Order after considering the competing proposals of the parties. We see no need, therefore, for modification of Judge Faman's schedule and believe that the Scheduling Order reflects the Court's views as to how the case should be managed.

Sincerely,



Linda A. Wadler

LAW/amn

cc: Mary B. Matterer, Esq. (via Facsimile)
Richard K. Herrmann, Esq. (via Facsimile)

EXHIBIT 16

**LAW OFFICES
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.**

901 New York Ave., NW
Washington, DC 20001

Telephone
(202) 408-4000

Facsimile
(202) 408-4400

FACSIMILE TRANSMITTAL

<u>TO</u>	<u>FROM</u>
Name: Daniel N. Kassabian, Esq.	Name: Linda A. Wadler, Esq.
Firm: Heller Ehrman LLP	Phone No.: (202) 408-4037
Fax No.: 415-772-1796	Fax # Verified by: A. Norris - MD 8113
Phone No.: 415-772-6098	# Pages (Incl. this): 1
Subject: Wyeth v. Impax	Date: August 1, 2006

Our File No.:

Confirmation Copy to Follow: NO

Message:

If there is a problem with this transmission, notify fax room at (202) 408-4174 or the sender at the number above.

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www.finnegan.com

LINDA A. WADLER
202.408.4037
linda.wadler@finnegan.com

August 1, 2006

Via Facsimile

Daniel N. Kassabian, Esq.
Heller Ehrman LLP
4350 La Jolla Village Drive, 7th Floor
San Diego, CA 92101

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 (D. Del.)

Dear Daniel:

I am writing in partial response to your July 31, 2006 letter with regard to the scheduling of a telephonic meet and confer. We are diligently working on Wyeth's response to issues Impax has raised and will respond in writing when we are able. For example, we only obtained permission from Impax to discuss its requested electronic search terms with Wyeth employees last week. Moreover, to request a next day verbal response to Impax's multiple and lengthy letters is not reasonable. Although we are not adverse to discussing issues over the telephone, because of the numerous issues that have been raised by both parties we believe it would be most efficient and less confusing to respond in writing. We request that Impax similarly provide us with their response to issues Wyeth has raised to date in writing as promptly as possible.

Sincerely,

A handwritten signature in cursive script, appearing to read 'Linda'.

Linda A. Wadler

LAW/amn

cc: Mary B. Matterer, Esq. (via facsimile)
Richard K. Herrmann, Esq. (via facsimile)

EXHIBIT 17

MORRIS, JAMES, HITCHENS & WILLIAMS LLP

222 Delaware Avenue, 10th Floor
Wilmington, Delaware 19801-1621
(302) 888-6800
Facsimile (302) 571-1750
www.morrisjames.com

Mary B. Matterer
(302) 888-6960
mmatterer@morrisjames.com

Mailing Address
P.O. Box 2306
Wilmington, DE 19899-2306

August 1, 2006

BY EMAIL AND FEDERAL EXPRESS

Henry C. Dinger, Esq.
Goodwin Procter
53 State Street
Boston, MA 02109
617.570.1276

RE: *Wyeth v. Impax Laboratories, Inc.*, Civil Action No. 06-222 JJF

Dear Mr. Dinger:

We represent Impax Laboratories, Inc. in a lawsuit pending in the United States District Court for the District of Delaware, *Wyeth v. Impax Laboratories, Inc.*, C.A. No. 06-222 JJF. In this lawsuit, Wyeth is asserting the same patents for an extended release formulation of venlafaxine hydrochloride that it asserted against Teva in the District of New Jersey in the case styled *Wyeth v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.*, No. 03-1293 ("Teva Litigation"). It is our understanding that you represented Teva in that litigation.

We have requested from Wyeth in discovery the transcripts of hearings and depositions conducted in connection with the Teva litigation, as well as the pleadings and exhibits introduced at hearings or depositions in the Teva litigation. We requested that Wyeth redact any information designated by Teva as confidential. Wyeth has refused to produce the materials, stating that "Teva has designated the bulk of this information as confidential and subject to the protective order in place in the Teva litigation." Wyeth contends that "under the protective order in that litigation, Teva, not Wyeth, would have to redact information it designated as confidential."

In order to facilitate discovery in our case, we request that Teva indicate which, if any, of the documents listed below contain Teva's confidential information:

- Docket No. 63: (Transcript of Proceedings held on 12/21/04 and 1/10/05 before Judge Shwartz)

Dover (302) 678-8815

Broom Street (302) 655-2599

Newark (302) 368-4200

Henry C. Dinger, Esq.
August 1, 2006
Page 2

MORRIS, JAMES, HITCHENS & WILLIAMS LLP

- Declaration of Lana A Shvartsman (including exhibits) and Memorandum of Law in Support of Defendant's Motion for Leave to File Amended Answers of April 1, 2005
- Docket No. 85 (Transcript of Proceedings held on 5/9/05 before Judge Shwartz)
- Docket No. 133 (Memorandum of Teva Defendants on Claim Construction)
- Docket No. 134 (Declaration of Eileen Quinn Steiner by Wyeth (including exhibits))
- Docket No. 136 (Wyeth's Opposition Markman Brief)
- Docket No. 123 (Transcript of Proceedings held on August 29, 2005 before Judge Martini)
- Docket No. 132 (Transcript of Proceedings held on September 20, 2005 before Judge Martini)
- Deposition Transcripts of the named inventors of the patents-in-suit
- Deposition Transcripts of Wyeth's 30(b)(6) witnesses Dr. Mangano and Mr. Alaburda
- Deposition Transcripts of Wyeth's expert witnesses
- Deposition Transcripts of Teva's expert witnesses
- Wyeth's expert reports disclosed pursuant to Fed. R. Civ. P. 26(a)(2)
- Teva's expert reports disclosed pursuant to Fed. R. Civ. P. 26(a)(2)
- Wyeth's interrogatory responses regarding claim construction, invalidity, and inequitable conduct
- Teva's interrogatory responses regarding claim construction, invalidity, and inequitable conduct

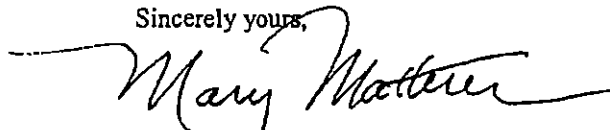
If Teva has designated any of these documents as confidential because they contain Teva confidential information, we request that Teva allow for their production in our pending litigation as confidential documents for trial counsel's eyes only pursuant to the District of Delaware's Local Civil Rule 26.2 and so indicate by reply letter. Alternatively, we request that Teva indicate which pages and lines should be redacted in order that such documents may be produced while preserving their confidentiality.

Henry C. Dinger, Esq.
August 1, 2006
Page 3

MORRIS, JAMES, HITCHENS & WILLIAMS LLP

Any cooperation Teva could lend us in this matter would help to avoid resort to judicial process to obtain these documents.

Sincerely yours,



Mary B. Matterer

cc: J. Anthony Downs, Esq. (via email and first class mail)
Roland H Schwillinski, Esq. (via email and first class mail)
Daryl L. Wiesen, Esq. (via email and first class mail)
Basil J. Lewis, Esq. (via email and first class mail)
Linda A. Wadler, Esq. (via email and first class mail)

EXHIBIT 18

002

GOODWIN | PROCTER

Henry C. Dinger, P.C.
617.570.1276
hdinger@
goodwinprocter.com

Goodwin Procter LLP
Counsellors at Law
Exchange Place
Boston, MA 02109
T: 617.570.1000
F: 617.523.1231

August 4, 2006

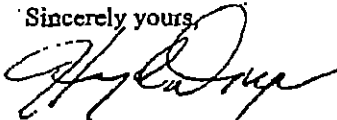
Mary B. Matterer, Esq.
Morris, James, Hitchens & Williams LLP
222 Delaware Avenue, 10th Floor
Wilmington, DE 19801-1621

Re: Wyeth v. Impax Laboratories, Inc., C.A. No. 06-222 JJF

Dear Ms. Matterer:

I have just returned to the office after several days out of town. I have your letter to me of August 3, 2006 concerning your request regarding Teva confidential information in deposition and hearing transcripts in *Wyeth v. Teva*. I have forwarded your request to my client, and I expect to be in a position to respond next week.

Sincerely yours,



Henry C. Dinger, P.C.

cc: Basil J. Lewis, Esq.
Linda A. Wadler, Esq.
Daryl L. Wiesen, Esq.

EXHIBIT 19

HellerEhrman_{LLP}

July 31, 2006

Via Facsimile & U.S. Mail

Samuel F. Ernst
Sam.Ernst@hellerehrman.com
Direct +1.415.772.6964
Direct Fax +1.415.772.1759
Main +1.415.772.6000
Fax +1.415.772.6268

40443.0005

Linda A. Wadler, Esq.
Finnegan Henderson Farabow Garrett
& Dunner LLP
901 New York Ave., NW
Washington, D.C. 20001-4413

Re: Wyeth v. Impax Laboratories, Inc.
U.S. District Court, District of Delaware, Civil Action No. 06-222 JJF

Dear Linda:

Because Wyeth has declined to agree to a modification of the Scheduling Order to allow the parties additional time to amend the pleadings, Impax requests that Wyeth produce the following discrete set of documents on an expedited basis, i.e., by Friday, August 4:

- Wyeth's New Drug Application No. 20-699 for Effexor XR, including the data in support of the three controlled clinical studies referenced in that Application: 600B-208-US, 600B-209-US, and 600B-367-EU.
- The transcripts from the depositions taken of the named inventors of the patents-in-suit in *Wyeth v. Teva Pharmaceuticals, USA, et al.* (No. 03-1293) ("Teva Litigation") and the transcripts from the depositions of Wyeth's 30(b)(6) witnesses in the Teva litigation, Dr. Mangano and Mr. Alaburda.
- The Proposed Amended Complaint submitted to the court by Teva in the Teva Litigation on or around April 1, 2005 as Exhibit D to a declaration of Lana Shvartsman.

These documents are responsive to Impax's Document Requests Nos. 3, 4, 29, and 48-50. They are, moreover, highly relevant to Impax's investigation into the potential defense of inequitable conduct.

There should be no reason to delay the immediate production of these documents. First, none of these documents should contain any information designated by Teva as confidential.

Heller Ehrman LLP 333 Bush Street San Francisco, CA 94104-2878 www.hellerehrman.com

Anchorage	Beijing	Hong Kong	Los Angeles	Madison, WI	New York	San Diego	San Francisco	Seattle
Silicon Valley	Singapore	Washington, D.C.						

HellerEhrman LLP

Linda A. Wadler, Esq.
July 31, 2006
Page 2

Second, in order to expedite the production of these documents, Impax is willing to set aside the parties' current disagreements regarding the format and costs of document productions. Specifically, Impax is willing to accept paper copies of these documents and to pay for the reasonable cost of producing these documents. To be clear, Impax does not waive its objections to Wyeth's insistence that documents be produced in TIFF format or hard copy or that Impax bear the costs of production with regard to the remainder of the documents Wyeth is obligated to produce in discovery. With regard to the discrete set of documents listed above, however, and due solely to the impending deadline for amendment of pleadings, Impax will accept paper copies and will pay for the reasonable cost of producing these documents.

Please let me know by this Wednesday, August 2 whether or not Wyeth will comply with this request. If not, we will move to compel and/or for an alteration in the Pretrial Schedule prior to the August 10 deadline.

Sincerely,


Samuel F. Ernst

07/31/2006 16:00 FAX

001

*** TX REPORT ***

TRANSMISSION OK

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CONNECTION TEL	43#0005#12024084400#
CONNECTION ID	
ST. TIME	07/31 15:59
USAGE T	01'00
PGS. SENT	3
RESULT	OK

HellerEhrman LLP

Facsimile Transmittal

333 Bush Street
San Francisco, CA 94104-2878
Main: +1.415.772.6000
Fax: +1.415.772.6268

To: Linda A. Wadler, Esq., Finnegan Henerson, et al., Washington, D.C.
Telephone: 1.202.408.4000 **Fax:** 1.202.408.4400

From: Samuel F. Ernst
Telephone: +1.415.772.6964

No. of Pages: 3 (including cover)
Date: July 31, 2006

40443.0005 (8004)

Message:

SF 1290979 v1
7/31/06 3:58 PM (40443.0005)

EXHIBIT 20

Case 2:03-cv-01293-WJM-RJH Document 74-2 Filed 04/01/2005 Page 1 of 2

LITE DePALMA GREENBERG & RIVAS, LLC

Allyn Z. Lite, Esq. (AL-6774)
Michael E. Patunas, Esq. (MP-2306)
Two Gateway Center, 12th Floor
Newark, New Jersey 07102-5003
(973) 623-3000

GOODWIN PROCTER LLP

J. Anthony Downs
Roland H. Schwillinski
Lana A. Shvartsman
53 State Street
Boston, MA 02109
(617) 570-1000

Attorneys for Defendants

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

WYETH,

Plaintiff,

vs.

TEVA PHARMACEUTICALS USA, INC., and
TEVA PHARMACEUTICAL INDUSTRIES,
LTD.,

Defendant.

:
:
:
:
:
:
:
:
:
:
:

Civil Action No. 03-1293 (FSH)

**CERTIFICATION OF
MICHAEL E. PATUNAS**

MICHAEL E. PATUNAS, of full age, hereby certifies as follows:

1. I am an attorney at law of the State of New Jersey and a member in good standing of the bar of this Court. I am a partner in the firm of Lite DePalma Greenberg & Rivas, LLC, co-counsel for Defendants in this matter.

2. I make this Certification on my personal knowledge in support of Defendants'

Case 2:03-cv-01293-WJM-RJH Document 74-2 Filed 04/01/2005 Page 2 of 2

motion to seal the Declaration of Lana A. Shvartsman and the Memorandum of Law in Support of Defendants' Motion for Leave to File Amended Answers, both dated April 1, 2005.

3. The materials that Defendants seek to seal include documents and information designated as "confidential" by Plaintiff pursuant to a Stipulation and Protective Order executed by the parties, entered by the Honorable Patty Shwartz, U.S.M.J. and filed with the Court.

4. By designating the documents and information as "confidential," Plaintiff has represented "that it reasonably and in good faith believes that the designated material constitutes or discloses its trade secrets or other confidential research, development, manufacture, regulatory, financial, commercial, marketing, or other business information within the meaning of Fed.R.Civ.P. 26(c)(7)."

5. Pursuant to the Stipulation and Protective Order, all materials that contain information designated by either party as "confidential" must be filed under seal.

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements are willfully false I am subject to punishment.

/s/ Michael E. Patunas
Michael E. Patunas

Dated: April 1, 2005

EXHIBIT 21

HellerEhrman^{LLP}

August 4, 2006

Via E-mail

Samuel F. Ernst
Sam.Ernst@hellerehrman.com
Direct +1.415.772.6964
Direct Fax +1.415.772.1759
Main +1.415.772.6000
Fax +1.415.772.6268

40443.0005

Linda A. Wadler, Esq.
Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
901 New York Ave., NW
Washington, DC 2001

Re: *Wyeth v. Impax Laboratories, Inc.*, No. 06-222

Dear Linda:

This letter is in response to your letters of August 2, 2006.

Our offer to pay for the cost of Wyeth producing a discrete number of documents on an expedited basis was expressly contingent on Wyeth's agreement to produce the documents on an expedited basis. In your letter of August 2, you refused to produce those documents on an expedited basis. Accordingly, we will not be paying for the cost of their production.

Wyeth's position that Impax should bear the cost of its document productions in this case is unreasonable given the enormous size and resources of Wyeth relative to Impax. Wyeth must have known that it would incur costs for discovery production at the time it initiated this lawsuit. Wyeth has already incurred much of the cost of gathering and processing documents because it has already gathered and produced many of the same responsive documents for the Teva litigation and has those documents on hand ready for production, as evidenced by the fact that Wyeth knows the exact population of those documents. Impax will not pay for the cost of Wyeth's document productions absent a court order. There is no basis in the Federal Rules for Wyeth to use this dispute as an excuse to delay its document production.

There is no basis for your refusal to produce the small group of documents we requested on an expedited basis. You state that you will wait to produce the deposition transcripts of the named inventors of Wyeth's patents-in-suit until Teva responds to our letter inquiring whether those transcripts contain Teva confidential information. Wyeth knows whether or not the transcripts contain information designated by Teva as confidential. If they

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Silicon Valley	Singapore	Washington, D.C.						

HellerEhrman LLP

Linda A. Wadler, Esq.
August 4, 2006
Page 2

do not, Wyeth should so state. Indeed, it is unlikely that this inventor deposition testimony would include Teva confidential information.

Wyeth's NDA for Effexor XR and the data in support thereof certainly do not contain Teva confidential information, and the fact that these documents may contain a large number of pages should be no impediment to their immediate production. In answer to your letter of August 2, 2006 inquiring as to when we will produce Impax's ANDA No. 78-057 to Wyeth, we have produced a disc containing that ANDA today via Federal Express, notwithstanding the fact that it contains a large number of pages.

Nor does the Proposed Amended Answer submitted by Teva in the Teva litigation contain information Teva deems confidential. Teva moved to file that document and the other documents in support of its motion for leave to amend under seal because "[t]he materials that Defendants seek to seal include documents and information designated as 'confidential' by Plaintiff," not Defendant Teva. Certification of Michael E. Patunas of Apr. 1, 2005 ¶ 3, Doc. No. 74-2 in *Wyeth v. Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd.*, No. 03-1293 (D.N.J.) (emphasis added). Wyeth's refusal to produce this document immediately because it was filed under seal by Teva is, therefore, disingenuous. Wyeth can produce this document immediately as confidential pursuant to Local Civil Rule 26.2.

We also note that we provided a draft Protective Order to you on July 12 and that we have not received comments. Please let us know if Wyeth agrees to its terms. If not, we request to make this a topic of the meet and confer Mr. Kassabian requested for this coming Monday.

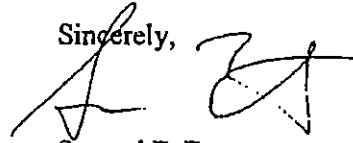
Wyeth's refusal to agree to a modification of the scheduling order pushing back the August 10 deadline to amend pleadings, in conjunction with the numerous barriers Wyeth has erected to prevent the timely production of documents, leave Impax little choice but to go to the Court for relief. We hope, however, that Wyeth will agree to one final telephonic meet and confer on Monday, August 7, as requested in Mr. Kassabian's letter of yesterday, to attempt to reach some sort of a compromise.

Regardless of whether Impax is able to obtain discovery from Wyeth prior to the August 10 deadline, we are prepared to file an Amended Answer and Counterclaim. Assuming Wyeth does not provide documents in a timely fashion, we will provide you with a proposed Amended Answer and Counterclaim early next week and ask that you either stipulate to its filing or indicate that Impax will be required to move for leave to amend.

HellerEhrman LLP

Linda A. Wadler, Esq.
August 4, 2006
Page 3

Sincerely,

A handwritten signature in black ink, appearing to be 'S. Ernst', written over a horizontal line.

Samuel F. Ernst

EXHIBIT 22

AUG 04 2006 16:56 FR FHFGD

2024084400 TO 14157726268#

P.01

**LAW OFFICES
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.**

901 New York Ave., NW
Washington, DC 20001

Telephone
(202) 408-4000

Facsimile
(202) 408-4400

FACSIMILE TRANSMITTAL

TO	FROM
Name: Daniel N. Kassabian, Esq.	Name: Robert A. Pollock, Esq.
Firm: Heller Ehrman LLP	Phone No.: (202) 408-4037
Fax No.: 415-772-6268	Fax # Verified by: A. Norris - MD 8113
Phone No.: 415-772-6098	# Pages (Incl. this): 2
Subject: Wyeth v. Impax	Date: August 4, 2006

Our File No.:

Confirmation Copy to Follow: YES

Message:

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AUG 04 2006 16:57 FR FHF6D

2024084400 TO 14157726268H

P.02



901 New York Avenue, NW • Washington, DC 20001-4413 • 202.408.4000 • Fax 202.408.4400
www.finnegan.com

ROBERT A. POLLOCK
202.408.4081
robert.pollock@finnegan.com

August 4, 2006

Daniel N. Kassabian, Esq.
Heller Ehrman LLP
333 Bush Street
San Francisco, CA 94104

**VIA FACSIMILE
CONFIRMATION VIA
FEDERAL EXPRESS**

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 (D. Del.)

Dear Daniel:

Further to Impax's letter of July 31, 2006, requesting paper copies of Wyeth's NDA No. 20-699, and as part of Wyeth's document production, I am enclosing as part of a rolling production one box of documents containing the following range of production numbers:

WYETH 004-000001 - WYETH 004-001360.1;
WYETH 004-001361 - WYETH 004-002397; and
WYETH 004-002400 - WYETH 004 003005.

The enclosed documents are stamped CONFIDENTIAL or HIGHLY CONFIDENTIAL and SUBJECT TO PROTECTIVE ORDER. Until a formal protective order is in place, however, the enclosed documents should be maintained on an outside counsel eyes only basis pursuant to D. Del. L.R. 26.2.

With respect to your July 31, 2006 agreement to reimburse us for the reasonable cost of providing paper copies of NDA No. 20-699 and other selected documents, the cost for providing the enclosed documents is \$180.18 (6¢ per page). Please reimburse us promptly for this amount.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Pollock', written over a horizontal line.

Robert A. Pollock

AUG 04 2006 16:57 FR FHF GD

2024084400 TO 14157726268#

P.03

Daniel N. Kassabian, Esq.
August 4, 2006
Page 2

FINNEGAN
HENDERSON
PARABOW
GARRETT &
DUNNELL

cc: Mary B. Matterer, Esq. (via Facsimile, without enclosures)
Richard K. Hermann, Esq. (via Facsimile, without enclosures)

EXHIBIT 23

AUG 08 2006 09:41 FR FHF6D

2024084400 TO 14157726268

P.01

LAW OFFICES
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.
801 New York Ave., NW
Washington, DC 20001

Telephone
(202) 408-4000

Facsimile
(202) 408-4400

FACSIMILE TRANSMITTAL

<u>TO</u>	<u>FROM</u>
Name: Daniel N. Kassabian, Esq.	Name: Robert Pollock, Esq.
Firm: Heller Ehman LLP	Phone No.: (202) 408-4081
Fax No.: 415-772-6268	Fax # Verified A. Norris - MD 8113
Phone No.: 415-772-6098	by: # Pages (incl. this): 4
Subject: Wyeth v. Impax	Date: August 8, 2006

Our File No.:

Confirmation Copy to Follow: NO

Message:

If there is a problem with this transmission, notify fax room at (202) 408-4174 or the sender at the number above.

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2024084400 TO 14157726268

P.02



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www.finnegan.com

ROBERT A. POLLOCK
202.408.4081
robert.pollock@finnegan.com

August 8, 2006

Daniel N. Kassabian, Esq.
Heller Ehrman LLP
333 Bush Street
San Francisco, CA 94104

**LETTER ONLY VIA FACSIMILE
CONFIRMATION WITH ENCLOSURES
VIA FEDERAL EXPRESS**

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 (D. Del.)

Dear Daniel:

Further to Impax's letter of July 31, 2006, requesting paper copies of Wyeth's NDA No. 20-699, and as part of Wyeth's document production, I am enclosing as part of a rolling production twenty boxes of documents containing the following range of production numbers:

WYETH 004 003006 - WYETH 004-004645;
WYETH 004-003990.1 - WYETH 004-003990.52;
WYETH 004-004647 - WYETH 004-006979;
WYETH 004-006982 - WYETH 004-012420;
WYETH 004-012430 - WYETH 004-013207;
WYETH 004-013210 - WYETH 004-014362.1;
WYETH 004-014363 - WYETH 004-018320;
WYETH 004-018323 - WYETH 004-019366.1;
WYETH 004-019367 - WYETH 004-019430.1;
WYETH 004-019431 - WYETH 004-019451.1;
WYETH 004-019452 - WYETH 004-020084;
WYETH 004-020098 - WYETH 004-020173;
WYETH 004-020183 - WYETH 004-020558;
WYETH 004-020558 - WYETH 004-021408;
WYETH 004-021410 - WYETH 004-023045;
WYETH 004-023048 - WYETH 004- 025098;
WYETH 004-025101 - WYETH 004-025550;
WYETH 004-025552 - WYETH 004-025574;
WYETH 004-025576 - WYETH 004-026996;
WYETH 004-026999 - WYETH 004-027910.1;

AUG 08 2006 09:41 FR FHF6D

2024084400 TO 14157726268

P.03

Daniel N. Kassabian, Esq.
August 8, 2006
Page 2

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNN LLP

WYETH 004-027911 - WYETH 004-028503.1;
WYETH 004-028504 - WYETH 004-029624;
WYETH 004-029625 - WYETH 004-030113;
WYETH 004-030114 - WYETH 004-031028.1;
WYETH 004-031029 - WYETH 004-031853;
WYETH 004-031855 - WYETH 004-033852;
WYETH 004-033854 - WYETH 004-033976;
WYETH 004-033978 - WYETH 004-034023;
WYETH 004-034025 - WYETH 004-034029;
WYETH 004-034040 - WYETH 004-034177;
WYETH 004-034179 - WYETH 004-034261.1;
WYETH 004-034262 - WYETH 004-036299;
WYETH 004-036301 - WYETH 004-036354;
WYETH 004-036358 - WYETH 004-036421;
WYETH 004-036424 - WYETH 004-038096;
WYETH 004-038099 - WYETH 004-038549.3;
WYETH 004-038550 - WYETH 004-038885;
WYETH 004-038887 - WYETH 004-043118;
WYETH 004-043187 - WYETH 004-044054;
WYETH 004-044056 - WYETH 004-044112;
WYETH 004-044115 - WYETH 004-047446;
WYETH 004-047449 - WYETH 004-047493;
WYETH 004-047495 - WYETH 004-047499;
WYETH 004-047501 - WYETH 004-047505;
WYETH 004-047507 - WYETH 004-047642;
WYETH 004-047646 - WYETH 004-047695;
WYETH 004-047697 - WYETH 004-047852;
WYETH 004-047854 - WYETH 004-047908;
WYETH 004-047908 - WYETH 004-047978;
WYETH 004-047980 - WYETH 004-047984;
WYETH 004-047986 - WYETH 004-047996;
WYETH 004-047998 - WYETH 004-048006;
WYETH 004-048008 - WYETH 004-048186;
WYETH 004-048188 - WYETH 004-048516;
WYETH 004-048518 - WYETH 004-048595;
WYETH 004-048597 - WYETH 004-048657;
WYETH 004-048662 - WYETH 004-048913;
WYETH 004-048915 - WYETH 004-049029;
WYETH 004-049031 - WYETH 004-049790;
WYETH 004-049837 - WYETH 004-049872;
WYETH 004-049874 - WYETH 004-049876;
WYETH 004-049878 - WYETH 004-049887;
WYETH 004-049889 - WYETH 004-050482;

AUG 08 2006 09:42 FR FHFGD

2024084400 TO 14157726268

P.04

Daniel N. Kassabian, Esq.
August 8, 2006
Page 3

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNE LLP

WYETH 004-050484 - WYETH 004-050510;
WYETH 004-050514 - WYETH 004-050548;
WYETH 004-050552 - WYETH 004-050582;
WYETH 004-050585 - WYETH 004-050591;
WYETH 004-050594;
WYETH 004-050597 - WYETH 004-050601;
WYETH 004-050602 - WYETH 004-052623;
WYETH 004-052625 - WYETH 004-052710;
WYETH 004-052716 - WYETH 004-053914;
WYETH 004-053926 - WYETH 004-053949;
WYETH 004-053958 - WYETH 004-055271;
WYETH 004-055274 - WYETH 004-055823;
WYETH 004-055836 - WYETH 004-057097;
WYETH 004-057114 - WYETH 004-057619;
WYETH 004-057629 - WYETH 004-057642;
WYETH 004-057647 - WYETH 004-058550; and
WYETH 004-058553 - WYETH 004-058753.

The enclosed documents are stamped CONFIDENTIAL or HIGHLY CONFIDENTIAL and SUBJECT TO PROTECTIVE ORDER. Until a formal protective order is in place, however, the enclosed documents should be maintained on an outside counsel eyes only basis pursuant to D. Del. L.R. 26.2.

With respect to your July 31, 2006 agreement to reimburse us for the reasonable cost of providing paper copies of NDA No. 20-699 and other selected documents, the cost for providing the enclosed documents is \$3,330.60 (6¢ per page). Please reimburse us promptly for this amount.

Sincerely,



Robert A. Pollock

RAP/amn

cc: Mary B. Matterer, Esq. (via Facsimile, without enclosures)
Richard K. Hermann, Esq. (via Facsimile, without enclosures)

EXHIBIT 24

HellerEhrman^{LLP}

August 4, 2006

Via Federal Express

Daniel N. Kassabian
Daniel.Kassabian@hellerehrman.com
Direct +1.415.772.6098
Direct Fax +1.415.772.1796
Main +1.415.772.6000
Fax +1.415.772.6268

40443.0005

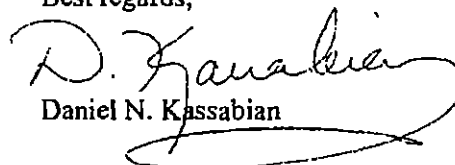
Linda A. Wadler, Esq.
Finnegan Henderson Farabow
Garrett & Dunner LLP
901 New York Avenue, NW
Washington, D.C. 20001-4413

Re: Wyeth v. Impax Laboratories, Inc.
U.S. District Court, District of Delaware, Civil Action No. 06-222 JJF

Dear Linda:

Please find enclosed a CD containing TIFF images and a Concordance load file of Impax's ANDA 78-057, Bates labeled IMPAX0000001 - IMPAX0004513. Please note that these documents have been marked "Confidential - Outside Counsel Eyes Only" pursuant to Local Rule 26.2, and should be treated accordingly until the parties can agree to a protective order in this action.

Best regards,


Daniel N. Kassabian

Enclosure

EXHIBIT 25

HellerEhrman_{LLP}

August 7, 2006

Via E-mail

Samuel F. Ernst
Sam.Ernst@hellerehrman.com
Direct +1.415.772.6964
Direct Fax +1.415.772.1759
Main +1.415.772.6000
Fax +1.415.772.6268

40443.0005

Linda A. Wadler, Esq.
Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
901 New York Ave., NW
Washington, DC 2001

Re: *Wyeth v. Impax Laboratories, Inc.*, No. 06-222

Dear Linda:

This is in response to your letter of today's date.

Our compromise offer in our letter of July 31, 2006 to pay for a discrete set of paper copies was conditioned on receiving the documents by August 4, 2006. You did not accept our compromise offer to pay for the production of paper copies of a discrete set of documents by Friday, August 4, 2006 for the following reasons:

- You did not agree to produce any of the documents by Friday, August 4, 2006 and have not produced them by that date.
- You have begun production of Wyeth's NDA, but only in a "rolling production" calculated to deprive Impax of the opportunity to analyze that document in time for the August 10 deadline for amending pleadings. Moreover, you have not produced this document as kept in the ordinary course of business and as submitted to the FDA, but, rather, as an uncollated mass of paper further calculated to deprive Impax of the opportunity to analyze it in time for the August 10 deadline. You did not produce the entire NDA on August 4, which was the condition for our offer to pay for its production.
- You have not produced the deposition transcripts by August 4 and you stated in your letter of August 2 that that you would not produce these transcripts until Teva agreed to their production, even though they plainly do not contain Teva's confidential information. To date we have received no deposition transcripts. You did not produce the deposition transcripts on August 4, which was the condition for our offer to pay for their production.

Heller Ehrman LLP 333 Bush Street San Francisco, CA 94104-2878 www.hellerehrman.com

Anchorage	Beijing	Hong Kong	Los Angeles	Madison, WI	New York	San Diego	San Francisco	Seattle
Silicon Valley	Singapore	Washington, D.C.						

Heller Ehrman LLP

Linda A. Wadler, Esq.
August 7, 2006
Page 2

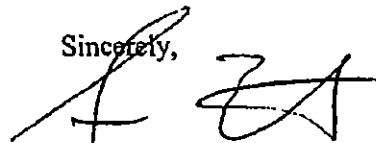
- You refuse to produce the Proposed Amended Complaint in the Teva litigation even though it contains no Teva confidential information. You did not produce this document on August 4, which was the condition for our offer to pay for its production.

In sum, because you have not produced any of these documents by August 4, 2006, which was the clear and unmistakable condition for our offer to pay for their production, we will not pay for their production.

Because Wyeth has not produced the documents Impax requested in a time or manner to allow Impax the opportunity to analyze them prior to the August 10 deadline, and because Wyeth has refused to stipulate to an extension of that deadline, we will move for a modification of the Scheduling Order. We will further move to compel production by Wyeth of documents in response to our document requests in their native format without the numerous restrictions and conditions Wyeth has imposed on its discovery obligations.

Impax will also seek to file an amended answer and counterclaims, which is enclosed herein. For your convenience, we have also enclosed a red-line version of the amended answer and counterclaims indicating what has been amended. Please advise us by this Wednesday morning if Wyeth will stipulate to our filing this pleading or if we will be forced to move the Court for leave to file.

Sincerely,

A handwritten signature in black ink, appearing to be 'S. Ernst', written over a horizontal line.

Samuel F. Ernst

Enclosures

EXHIBIT 26

Case 2:03-cv-01293-WJM-RJH Document 26 Filed 01/14/2004 Page 1 of 24

Kevin J. McKenna, Esq. (KM 7330)
 GIBBONS, DEL. DEO, DOIAN,
 GRIFFINGER & VECCHIONE, P.C.
 One Riverfront Plaza
 Newark, NJ 07102-5496
 Tel.: (973) 596-4500
 Fax: (973) 596-0545
 Attorneys for Plaintiff Wyeth

IN THE UNITED STATES DISTRICT COURT
 FOR THE DISTRICT OF NEW JERSEY

WYETH

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.

Defendant.

Civil Action No.: 03-1293 (KSH)

STIPULATION AND
PROTECTIVE ORDER

WHEREAS, Plaintiff Wyeth and Defendant Teva Pharmaceuticals USA, Inc. have, through counsel, stipulated to the entry of this Protective Order to prevent the unnecessary dissemination or disclosure of certain documents, things and information in the possession, custody, or control of a party or non-party that constitute or contain trade secrets or other confidential research, development, manufacture, regulatory, financial, marketing, commercial or other competitive information within the meaning of Rule 26(c)(7) of the Federal Rules of Civil Procedure ("Fed. R. Civ. P."); and

WHEREAS, the parties, through counsel, stipulate that good cause exists for the entry of this Protective Order pursuant to Rule 26(c)(7), Fed. R. Civ. P. to protect against improper disclosure or use of confidential information produced or disclosed in this case, see *Pansy v.*

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Borough of Stroudsburg, 23 F.3d 772 (3d Cir. 1994); Glennede Trust Co. v. Thompson, 56 F.3d 476 (3d Cir. 1995):

IT IS HEREBY STIPULATED AND AGREED, SUBJECT TO THE APPROVAL AND ORDER OF THE COURT as follows:

1. This Protective Order shall apply to all information, documents, and things within the scope of discovery in this action, including, without limitation, all testimony adduced at depositions, documents or things responsive to requests for the production of documents and things, answers to interrogatories, responses to requests for admission, and all other discovery taken pursuant to the Federal Rules of Civil Procedure, as well as hearing or trial transcripts, matters in evidence, and any other information furnished, directly or indirectly, by or on behalf of any party to this action or any non-party to the extent such information, documents, and things are designated "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL" in accordance with this Protective Order.

2. This Protective Order creates two levels of confidentiality. As used herein, "CONFIDENTIAL" material means trade secrets or other confidential research, development, manufacture, regulatory, financial, commercial, marketing, business information, or know-how, as well as any other confidential technical or non-technical subject matter within the meaning of Fed. R. Civ. P. 26(c)(7). The designation of "CONFIDENTIAL" by the producing party constitutes the representation of that party that it reasonably and in good faith believes that the designated material constitutes or discloses its trade secrets or other confidential research, development, manufacture, regulatory, financial, commercial, marketing, or other business information within the meaning of Fed. R. Civ. P. 26(c)(7).

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As used herein, "HIGHLY CONFIDENTIAL" material shall be limited to highly sensitive business information relating to projected future sales, pricing, volumes, revenues, costs or profits for future sales of venlafaxine hydrochloride extended release products. The designation of "HIGHLY CONFIDENTIAL" by the producing party constitutes the representation of that party that it reasonably and in good faith believes that the designated material constitutes or discloses highly sensitive projected pricing, sales, volume, revenue, cost, or profit information for future sales of venlafaxine hydrochloride extended release products.

3. If a third party or non-party provides discovery to any party in connection with this action, and if the third party or non-party so elects, then the provisions of this Protective Order which are available to a producing party shall apply to such discovery and the parties will treat all HIGHLY CONFIDENTIAL or CONFIDENTIAL material of such a third party or non-party, which information is designated as HIGHLY CONFIDENTIAL or CONFIDENTIAL, in accordance with the terms of this Protective Order. Under such circumstances, the third party or non-party shall have the same rights and obligations under this Protective Order as held by the parties to this action.

4. The parties and any third party shall label or mark documents and things that constitute or contain HIGHLY CONFIDENTIAL material with the legend "HIGHLY CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER." The parties and any third parties shall label or mark documents and things that constitute or contain CONFIDENTIAL material with the legend "CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER," or otherwise explicitly designate the materials as CONFIDENTIAL and subject to the Protective Order. Each page of each document and each thing that constitutes or contains HIGHLY CONFIDENTIAL or CONFIDENTIAL material shall be labeled or marked with the appropriate legend "HIGHLY

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~~CONFIDENTIAL-SUBJECT TO PROTECTIVE ORDER~~" or ~~"CONFIDENTIAL-SUBJECT TO PROTECTIVE ORDER"~~ when the document or thing is produced to the party or parties seeking discovery. Anything that cannot be so marked on its face shall be marked by placing the appropriate legend on a container or package in which the thing is produced or on a tag attached thereto. Each page of each document and each thing produced pursuant to discovery in this action shall bear a unique identifying number.

Documents and things produced without a legend designating the material ~~HIGHLY CONFIDENTIAL~~ or ~~CONFIDENTIAL~~ shall not be subject to this Protective Order unless otherwise agreed by the parties or ordered by the Court, or otherwise designated ~~HIGHLY CONFIDENTIAL~~ or ~~CONFIDENTIAL~~ in accordance with the provisions of paragraph 7 of this Protective Order.

Inspection of documents or things by any party shall be conducted by outside counsel eligible under paragraph 12 below. Such outside counsel shall treat all information in such documents or things as ~~CONFIDENTIAL~~ material until copies are produced. After copies are produced, the information in such documents or things will be treated consistent with any legend produced on each document or thing.

5. Any response to written interrogatories or requests for admission or any testimony adduced at a deposition upon written questions (or any portion of any of the foregoing) that constitutes or contains ~~HIGHLY CONFIDENTIAL~~ or ~~CONFIDENTIAL~~ material shall be labeled or marked with the legend ~~"HIGHLY CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER"~~ or ~~"CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER"~~ by the party providing the response or testimony on the first page of that document near the caption. Any response or testimony that constitutes or contains ~~HIGHLY CONFIDENTIAL~~ or

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CONFIDENTIAL material shall be labeled or marked on the first page with the appropriate legend when the response or testimony is served upon the party seeking discovery. If the response or testimony contains HIGHLY CONFIDENTIAL material, the specific pages (or portions of pages) containing that material shall be clearly designated on each page so that in-house counsel for the parties can be provided with a redacted version of the document containing only CONFIDENTIAL or non-confidential material. Responses or testimony served without a legend on the first page designating the material confidential shall not be HIGHLY CONFIDENTIAL or CONFIDENTIAL subject to this Protective Order unless otherwise agreed by the parties or ordered by the Court, or otherwise designated HIGHLY CONFIDENTIAL or CONFIDENTIAL in accordance with the provisions of paragraph 7 of this Protective Order.

6. ~~With respect to testimony adduced at depositions upon oral examination of current or former directors, officers, employees, or agents of the parties, and with respect to testimony adduced at depositions upon oral examination of current consultants or experts of the parties, all deposition transcripts automatically will be deemed and treated as CONFIDENTIAL. The parties agree to mark the first page of all copies of deposition transcripts with the legend "CONFIDENTIAL -- SUBJECT TO PROTECTIVE ORDER".~~

In the event that testimony adduced at a deposition contains or constitutes HIGHLY CONFIDENTIAL material, counsel for the designating party shall instruct the court reporter to mark the specific pages (or portions of pages) of all copies of deposition transcripts containing HIGHLY CONFIDENTIAL material with the legend "HIGHLY CONFIDENTIAL -- SUBJECT TO PROTECTIVE ORDER" and to mark the first page of the deposition transcript with the legend "HIGHLY CONFIDENTIAL -- SUBJECT TO PROTECTIVE ORDER at page _____."

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Counsel for the designating party may also request that all persons other than the witness, the court reporter, those individuals specified in paragraphs 12 and 13, and counsel for the witness of a non-party witness leave the deposition room during the portion of the deposition which inquires into matters deemed "CONFIDENTIAL" by the designating party. The failure of individuals other than those specified in the previous sentence to leave the deposition room during any portion of the deposition which inquires into matters deemed "CONFIDENTIAL" by the designating party shall constitute justification for counsel to instruct the witness that he or she shall not answer the question. In addition, counsel for the designating party may request that in future sessions for other parties (when the deposition occurs during any portion of the deposition which inquires into matters deemed "HIGHLY CONFIDENTIAL" by the designating party). The failure of the witness to leave the deposition room during any portion of the deposition which inquires into matters deemed "HIGHLY CONFIDENTIAL" by the designating party shall constitute justification for counsel to instruct the witness that he or she shall not answer the question.

If a party through inadvertence produces or provides discovery of any "HIGHLY CONFIDENTIAL" or "CONFIDENTIAL" material without labeling or marking it with the legends "HIGHLY CONFIDENTIAL - SUBJECT TO THE PROTECTIVE ORDER" or "CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER" as provided in paragraphs 4-6 of the Protective Order, the producing party may give written notice to the receiving party or parties that the document, thing or other discovery information, response, or testimony is "HIGHLY CONFIDENTIAL" or "CONFIDENTIAL" and should be treated as such in accordance with the provisions of this Protective Order. Upon receipt of such notice and properly marked documents within ten (10) days after discovery of the inadvertent production, the receiving party

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or parties shall return and unmarked documents and things to the court pro se, and not retain copies thereof, in or out of such documents, things, information, responses, and testimony as HIGHLY CONFIDENTIAL or CONFIDENTIAL and shall undertake a best effort to correct any disclosure of such information contrary to the restrictions. Prior to receipt of such notice, disclosure of such documents, things, information, responses, and testimony to persons not authorized to receive HIGHLY CONFIDENTIAL or CONFIDENTIAL material shall not be deemed a violation of this Protective Order.

3. Nothing herein shall bar or otherwise restrain any attorney from rendering advice in a particular case in this action and in the course thereof, relying upon such attorney's examination of HIGHLY CONFIDENTIAL or CONFIDENTIAL material, provided, however, that in rendering such advice and in otherwise communicating with such client, the attorney shall not discuss any HIGHLY CONFIDENTIAL or CONFIDENTIAL material to unauthorized persons.

4. Nothing contained in this Protective Order shall be construed to affect or govern the scope of discovery in this action, or to preclude any party from moving the Court for a *check order* pursuant to Fed. R. Civ. P. 26(c) or any other provision of the Federal Rules of Civil Procedure. Nothing contained in this Protective Order shall be construed to require production or disclosure of any HIGHLY CONFIDENTIAL or CONFIDENTIAL material deemed by counsel for the party possessing such material to be protected from disclosure by the attorney-client privilege or the attorney work product immunity or of material the disclosure of which might constitute a breach of an agreement with a third party or non-party, so long as that withheld material is excluded in the manner required by the Federal Rules of Civil Procedure.

attjle)

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by the producing party. This Protective Order shall not preclude any party from moving the Court for an order compelling production or disclosure of such material.

10. If a producing party inadvertently or mistakenly produces information, documents, or tangible items in this Action that should have been withheld subject to a claim of attorney-client privilege or work product immunity, such production shall in no way prejudice or otherwise constitute a waiver of, or estoppel as to, any claim of privilege or work-product immunity for such information. In such an event, the producing party shall request, in writing, within five (5) business days of discovery of such inadvertent or mistaken production, the return of all information for which a claim of inadvertent or mistaken production is made. Within five (5) business days of receiving a written request to do so from the producing party, the receiving party shall return to the producing party any documents or tangible items that the producing party represents are covered by a claim of attorney-client privilege or work product immunity and were inadvertently or mistakenly produced. The receiving party also shall destroy any extra copies or summaries of, or notes relating to, any such inadvertently or mistakenly produced information. The receiving party may move the Court for an Order compelling the production of such information, but such a motion does not relieve the receiving party of complying with the immediately preceding two sentences of this Order. The producing party shall retain copies of all returned documents and tangible things, and if such a motion is filed by the receiving party, shall provide copies to the Court of the documents, things, or information which are the subject of the motion. If the producing party fails to request the return of inadvertently or mistakenly produced documents within five (5) business days of discovery of the inadvertent or mistaken production and the receiving party does not return those documents upon the producing party's request, the producing party may request that the Court issue an order compelling the return or

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destruction of all copies of the inadvertently or mistakenly produced documents or things.

Notwithstanding the above, recognizing the need for the parties to prepare for their cases based on the discovery that is produced, if any information, document, or tangible thing is used in a court hearing, deposition, as an exhibit to a motion, is referenced in an expert report or pretrial order, or is otherwise used openly in the case, any claim of inadvertent production must be made within ten (10) business days after such use.

11. Material marked, labeled, or otherwise designated **HIGHLY CONFIDENTIAL** or **CONFIDENTIAL** as described in paragraphs 2 through 7 of this Protective Order may be used in testimony or trial, offered into evidence at trial and/or hearings on motions, and may be used to prepare for and conduct discovery, to prepare for trial and to support or oppose any motion in this action, but shall be subject to paragraphs 12 through 23 below and to any further order regarding confidentiality that the Court may enter. Use at trial of such material shall be governed by this Protective Order. Such material shall remain confidential at trial, and during any appeals of this action, and may not be used for any purpose or in any manner other than as permitted by this Protective Order or by further Order of the Court. At the request of a producing party, any person(s) not permitted access to **HIGHLY CONFIDENTIAL** or **CONFIDENTIAL** material under paragraph 12 may be barred from attending any portion of trial, any motion hearing, or depositions at which **HIGHLY CONFIDENTIAL** or **CONFIDENTIAL** material is revealed, subject to any further Order regarding confidentiality as this Court may enter.

12. Material marked, labeled or otherwise designated **HIGHLY CONFIDENTIAL** as described in paragraphs 2 through 7 of this Protective Order shall be deemed and treated as **HIGHLY CONFIDENTIAL**, unless and until the Court rules to the contrary, and accers thereto

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or disclosure thereof shall be limited to the following groups, unless and until the Court rules that there may be further disclosure:

(a) Outside counsel of record for the parties in this action (defined as attorneys from the following firms who have or are working on the present litigation), and their stenographic, clerical, and paralegal employees or agents whose duties and responsibilities require access to material designated **HIGHLY CONFIDENTIAL**:

Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.;

Gibbons, DelDeo, Dolan, Griffinger & Vecchione, P.C.;

Lite DePalma Greenberg & Rivas, L.L.C.; and

Goodwin Procter, L.L.P.;

provided that such attorneys, aside from their responsibilities in connection with this lawsuit, have (1) no competitive decision-making authority with respect to product design, marketing, pricing, or sales decisions concerning EFFEXOR® XR or Teva's extended release venlafaxine capsules and (2) no patent prosecution responsibility in the technology area of extended release formulations of venlafaxine. Restrictions (1) and (2) shall extend until one year after the termination of this litigation, including any appeals. Nothing in this paragraph precludes outside counsel for Wyeth or Teva from participation in other litigation or inter partes proceedings involving venlafaxine. To the extent any Wyeth or Teva patent claims are presented for the first time or are amended during such inter partes proceedings, counsel having access to **HIGHLY CONFIDENTIAL** and/or **CONFIDENTIAL** material may continue to participate in such inter partes proceedings but shall not participate in the drafting of any such claims.

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(b) Independent outside experts to the parties who are not current employees of any of the parties to this litigation or any present divisions, subsidiaries, parents, or affiliates of any of the parties to this litigation, whose advice and consultation are being or will be used in connection with this action, including their stenographic and clerical personnel;

(c) Courts before which this action is pending and their authorized staff and court reporters;

(d) Any interpreter or translator, including any typist or transcriber used by the interpreter or translator;

(e) Any litigation consultant, outside exhibit preparation company, or litigation study group retained by the parties for litigation support; and

(f) Outside copying services;

If counsel wish to disclose material designated HIGHLY CONFIDENTIAL or CONFIDENTIAL to the persons described in subparagraphs (b), (d), or (e) above, counsel shall first obtain a signed Undertaking in the form of the annexed Exhibit A from each such person who would require access to material designated HIGHLY CONFIDENTIAL or CONFIDENTIAL. In the case of the persons described in subparagraphs (b) or (e), the Undertaking shall be signed by the company, firm, or group retained by the party, and a single Undertaking by the company, firm, or group shall be sufficient to cover all employees or other individuals paid by the company, firm, or group. Counsel retaining the persons described in subparagraphs (b), (d), or (e) shall retain the original of each such signed Undertaking. Service of the Undertaking shall not be required.

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Material marked, labeled or otherwise designated CONFIDENTIAL as described in paragraphs 2 through 7 of this Protective Order shall be deemed and treated as CONFIDENTIAL, unless and until the Court rules to the contrary, and access thereto or disclosure thereof shall be limited to the following groups, unless and until the Court rules that there may be further disclosure:

- (a) the persons entitled to receive HIGHLY CONFIDENTIAL material identified above, and;
- (b) the following in-house counsel of both parties, and their stenographic or clerical employees whose duties and responsibilities require access to material designated CONFIDENTIAL:

For Wyeth:

- (1) Lawrence Stein, Esq.,
- (2) David Manupelizer, Esq.,
- (3) Susan Lee, Esq., and
- (4) Lawrence Alaburda, Esq.;

For Teva Pharmaceuticals USA, Inc.:

- (1) Richard Egoni, Esq.,
- (2) David Stark, Esq., and
- (3) Alicia Ashfield, Esq.;

provided that such attorneys, aside from their responsibilities in connection with this lawsuit, have (1) no competitive decision making authority with respect to product design, marketing, pricing, or sales decisions concerning EFFEXOR® XR or Teva's extended release venlafaxine capsules and (2) no patent prosecution responsibility in the

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technology area of extended release formulations of venlafaxine. Restrictions (1) and (2) shall extend until one year after the termination of this litigation, including any appeals. Nothing in this paragraph precludes the above-identified in-house counsel for Wyeth or Teva from participation in other litigation or inter partes proceedings involving venlafaxine. To the extent any Wyeth or Teva patent claims are presented for the first time or are amended during such inter partes proceedings, counsel having access to CONFIDENTIAL material may continue to participate in such inter partes proceedings but shall not participate in the drafting of any such claims.

The recipient of any HIGHLY CONFIDENTIAL or CONFIDENTIAL material shall maintain such information in a secure and safe area and shall exercise the same standard of due and proper care with respect to the storage, custody, use, and/or dissemination of such information as is exercised by the recipient with respect to his/her/its own proprietary information.

13. The parties also recognize that, in order to assist in the preparation of their respective cases, counsel may desire to utilize the services of an agent to perform computerized legal support and management services, including vendors retained by counsel for Plaintiff or Defendant, for the purpose of encoding, loading into a computer and storing and maintaining for information control and retrieval purposes, transcripts of depositions, hearings, trials, pleadings, exhibits marked by any party, briefs and accompanying affidavits and appendices, documents produced by any party, or attorneys' work product, all of which may contain HIGHLY CONFIDENTIAL or CONFIDENTIAL material. Such disclosure shall be made only on the following conditions. Any such vendor shall be a vendor regularly engaged in the provision of

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computerized legal support and management services, and shall not be engaged in the research, development, manufacture, marketing, or sale of pharmaceutical products.

Counsel desiring to disclose HIGHLY CONFIDENTIAL or CONFIDENTIAL material to a vendor for the purposes of this paragraph shall first obtain a signed Undertaking in the form of Exhibit A attached hereto, from a representative of the vendor who may require access to such material. Counsel retaining the vendor shall retain the original of each such signed Undertaking. Service of the Undertaking shall not be required.

The vendor shall be required to return to the party's counsel all copies of transcripts or other documents containing HIGHLY CONFIDENTIAL or CONFIDENTIAL material as soon as the information contained therein has been encoded and loaded into the computer.

The vendor shall be required to provide limited and secured access to the information stored in the computer, and the vendor shall guarantee that the vendor will supply access codes only to those persons associated with the party retaining or employing the vendor and who are entitled, under this Protective Order, to have access to HIGHLY CONFIDENTIAL or CONFIDENTIAL material and that only persons in possession of said access codes can obtain access to the information stored in the computer.

14. In the event that the parties (which in the case of HIGHLY CONFIDENTIAL or CONFIDENTIAL material produced and so designated by a third party or non-party, shall include such third party or non-party) desire to provide access to or disseminate HIGHLY CONFIDENTIAL or CONFIDENTIAL material to any person not otherwise entitled to access under this Protective Order, the parties may, without leave of the Court, unanimously agree (among all parties designating the material HIGHLY CONFIDENTIAL or CONFIDENTIAL) to allow such access, or in the absence of unanimous agreement, any party may move the Court for

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an Order that such person be given access thereto. In the event that the motion is granted, such person may have access to HIGHLY CONFIDENTIAL or CONFIDENTIAL material after first signing an Undertaking in the form of Exhibit A attached hereto. Counsel for the disclosing party shall retain the original of each such signed Undertaking.

Notwithstanding the preceding paragraphs, HIGHLY CONFIDENTIAL or CONFIDENTIAL material of a producing party may be disclosed to and/or used to examine, at deposition and at trial (or other court hearing): (a) an individual who either prepared, received, or reviewed the HIGHLY CONFIDENTIAL or CONFIDENTIAL material prior to the filing of this action or previously had access to or knowledge of the HIGHLY CONFIDENTIAL or CONFIDENTIAL material, as demonstrated by the HIGHLY CONFIDENTIAL or CONFIDENTIAL material itself or foundation testimony elicited during a deposition or trial; (b) an officer or employee of the producing party; and/or (c) an outside expert retained by the producing party. A party may disclose or use in any manner or for any purpose, any information or documents from that party's own files which the party itself has designated HIGHLY CONFIDENTIAL or CONFIDENTIAL.

15. Material designated HIGHLY CONFIDENTIAL or CONFIDENTIAL, including all information derived therefrom, and all copies, summaries, abstracts, excerpts, indices, and descriptions of such material shall be held in confidence by the receiving party, shall be used only by persons permitted access to it under this Protective Order, shall not be disclosed by the receiving party to any party or person not entitled under the terms of this Protective Order to have access to such material, shall not be used for any purpose other than in connection with this action, and shall not be used in any way for any research, development, manufacture, patent

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filing or prosecution, financial, commercial, marketing, business, regulatory, or other competitive purpose.

16. If HIGHLY CONFIDENTIAL or CONFIDENTIAL material is disclosed to or comes into the possession of any person not authorized to receive such information under this Protective Order, the party responsible for the disclosure shall (a) within five (5) business days of the discovery of such disclosure inform the designating party of all pertinent facts relating to such disclosure, including the identity of the unauthorized person or party who received such disclosure; (b) use reasonable efforts to obtain the prompt return of any such HIGHLY CONFIDENTIAL or CONFIDENTIAL material and to bind such unauthorized person or party to the terms of this Protective Order, and (c) within three (3) business days of the discovery of such disclosure, inform such unauthorized person or party of all provisions of this Protective Order, and request such unauthorized person or party to sign the Undertaking in the form attached hereto as Exhibit A. The executed Undertaking shall be served upon counsel of record for the producing party within five (5) business days of its execution by the person or party to whom HIGHLY CONFIDENTIAL or CONFIDENTIAL material was disclosed. The requirements set forth in this Paragraph shall not prevent the producing party from applying to the Court for further or additional relief.

17. If any material designated HIGHLY CONFIDENTIAL or CONFIDENTIAL is to be filed with the Court in connection with any proceedings herein, such material shall be filed with the Clerk of the Court in sealed envelopes or containers prominently marked with the caption of the case, a general description of the contents of the envelope or container and the following legend, or shall otherwise be filed under seal in accordance with the Local Rules or practice of the court in which the information is filed:

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"Contains CONFIDENTIAL (and/or HIGHLY CONFIDENTIAL, as appropriate)

Material To Be Opened Only By Or As Directed By The Court.

Civil Action No. 03-1293 (KSH) D. N.J."

In addition, any document that is to be filed with the Court and that contains HIGHLY CONFIDENTIAL or CONFIDENTIAL material shall be marked "FILED UNDER SEAL" on its cover page. Material designated HIGHLY CONFIDENTIAL or CONFIDENTIAL and filed under seal shall be maintained separate from the public records in this action and shall be released only to Court personnel, to persons entitled to have access to such materials under this Protective Order, or as further ordered by the Court.

Unless the Court orders otherwise, attendance at a hearing or at a trial session in this action at which material designated HIGHLY CONFIDENTIAL or CONFIDENTIAL will be used or disclosed shall be limited to individuals entitled to have access to such materials under the terms of this Protective Order.

18. The acceptance by Plaintiff or Defendant of material designated HIGHLY CONFIDENTIAL or CONFIDENTIAL shall not constitute an admission or concession, or permit an inference that such material is, in fact, confidential. Any receiving party may at any time request that the designating party cancel the HIGHLY CONFIDENTIAL or CONFIDENTIAL designation with respect to any document, object or information. Such request shall be made to counsel for the designating party in writing, and shall particularly identify the designated HIGHLY CONFIDENTIAL or CONFIDENTIAL material that the receiving party contends is not confidential and the reasons supporting its contention. This Protective Order shall not be construed to foreclose any party from moving the Court for an order that material designated HIGHLY CONFIDENTIAL or CONFIDENTIAL is not

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confidential. If the designating party does not agree to remove the HIGHLY CONFIDENTIAL or CONFIDENTIAL designation within ten (10) business days, then the party contending that such documents or material are not confidential may request by motion that the Court remove such material from the restrictions of this Protective Order. On such a motion, the party asserting confidentiality shall have the burden of proving that the material designated HIGHLY CONFIDENTIAL or CONFIDENTIAL constitutes or contains trade secrets or other confidential research, development, or commercial information within the meaning of Rule 26(c)(7) of the Federal Rules of Civil Procedure.

19. This Protective Order shall not be construed to prevent any of the parties, or any third party or non-party, from applying to the Court for relief therefrom, or from applying to the Court for further or additional protective orders, or from agreeing between or among themselves to modifications of this Protective Order, subject to the approval of the Court. The Protective Order shall not preclude the parties from enforcing their rights against any other party or any third party or non-party believed to be violating their rights. It is expressly understood between counsel for the parties that the personnel set forth in paragraph 12 or 13, *supra*, may be increased by unanimous agreement of the parties to this action without leave of the Court, or upon a showing, subject to the approval of the Court, by either Plaintiff or Defendant that such modification is necessary. Nothing herein shall prevent any party from disclosing its own HIGHLY CONFIDENTIAL or CONFIDENTIAL material in any manner it is considers appropriate.

20. With respect to any HIGHLY CONFIDENTIAL or CONFIDENTIAL material, this Protective Order shall survive the final termination of this action to the extent the information in such material is not or does not become known to the public and continues to be

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binding upon all persons to whom HIGHLY CONFIDENTIAL or CONFIDENTIAL material is disclosed hereunder. Upon final termination of this action, including all appeals, receiving outside counsel may retain one copy or sample of all material designated HIGHLY CONFIDENTIAL or CONFIDENTIAL for reference in the event of disputes over the use or disclosure of such material, and may retain copies of all papers filed with the Court, all other pleadings, all deposition transcripts, all expert reports, and all trial exhibits; and may also retain copies of other HIGHLY CONFIDENTIAL or CONFIDENTIAL documents, things, copies, and samples to the extent they include or reflect the receiving attorney's work product. Upon final termination of this action, including all appeals, however, all other copies and samples of material designated HIGHLY CONFIDENTIAL or CONFIDENTIAL that were not filed with the Court or that do not include or reflect the receiving attorneys' work product shall be assembled and returned (except for any that may be retained by the Court) to the producing party; counsel for the receiving party alternatively may certify in writing the destruction thereof. Accordingly, upon final termination of this action, no one other than outside counsel shall retain any copies or samples of any material designated HIGHLY CONFIDENTIAL or CONFIDENTIAL. As to HIGHLY CONFIDENTIAL or CONFIDENTIAL material stored in computer databases or backup tapes or disks, located, stored, or accessible by any persons other than outside counsel for the receiving party, the receiving party shall delete all such HIGHLY CONFIDENTIAL or CONFIDENTIAL material or otherwise disable access to such material.

21. The restrictions and obligations set forth herein relating to material designated HIGHLY CONFIDENTIAL or CONFIDENTIAL by the parties to this action shall not apply to any information of the parties which: (a) the producing or designating party or parties agree(s) should not be designated as HIGHLY CONFIDENTIAL or CONFIDENTIAL; (b) the producing

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or designating party or parties agree(s), or the Court rules, is already public knowledge; (c) the producing or designating party or parties agree(s), or the Court rules, has become public knowledge other than as a result of disclosure by the receiving party, its employees or agents in violation of this Protective Order; or (d) the producing or designating party or parties agree(s), or the Court rules, has come or shall come into the receiving party's legitimate knowledge or possession independently of the producing party under conditions such that its use and/or public disclosure by the receiving party would not violate some obligation to another. The restrictions and obligations set forth herein shall not prohibit discussions of any material designated HIGHLY CONFIDENTIAL or CONFIDENTIAL with any person who already has or obtains legitimate possession thereof.

22. This Protective Order has been agreed to by the parties to facilitate discovery and the production of relevant evidence in this action. Neither the agreement of the parties, nor the designation of any information, document, or the like as HIGHLY CONFIDENTIAL or CONFIDENTIAL material, nor the failure to make such designation, shall constitute evidence with respect to any issue in this action.

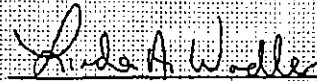
23. If another court or administrative agency issues a subpoena or orders production of any HIGHLY CONFIDENTIAL or CONFIDENTIAL material received by a party pursuant to this Protective Order, the receiving party shall promptly notify the producing party of the pendency of such subpoena or order.

By:


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Mark E. Zarzali, Esq.
GIBBONS, DELDEO, DOLAN,
GRYFFINGER & VECCHIONE, P.C.
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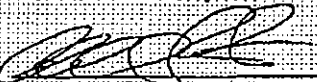
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By:



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Counsel for Defendant Teva
Pharmaceuticals USA, Inc.

SO ORDERED this 13th day of January, 2004.


United States District Judge
PJM

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EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

WYETH

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

Civil Action No. 03-1293 (KSH)

UNDERTAKING OF

STATE OF

COUNTY OF

SS:

I, _____, being duly sworn, state that:

1. My present address is _____ My present
employer is _____, and the address of my present employer

My present occupation is _____

2. I have received a copy of the Protective Order in this action. I have carefully read
and understand the provisions of the Protective Order.

3. I will comply with all of the provisions of the Protective Order and hereby submit
to the jurisdiction of the United States District Court for the District of New Jersey for the

022510_1

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purpose of the enforcement of the Protective Order in this action. I will hold in confidence, will not disclose to anyone not qualified under the Protective Order, and will use only for purposes of this action, any HIGHLY CONFIDENTIAL or CONFIDENTIAL material, including the substance and any copy, summary, abstract, excerpt, index or description of such material, that is disclosed to me as well as any knowledge or information derived from any of the above mentioned items. I will take reasonable steps to restrict access to any HIGHLY CONFIDENTIAL or CONFIDENTIAL information to only those persons authorized by the Protective Order to have such access.

4. I will return all HIGHLY CONFIDENTIAL or CONFIDENTIAL material that comes into my possession, and all documents and things that I have prepared relating thereto, to counsel for the party by whom I am employed or retained or from whom I received such material when requested to do so.

5. I understand that if I violate the provisions of the Protective Order, I will be subject to sanctions by the Court and that the parties, or either of them, may assert other remedies against me. I hereby submit to the jurisdiction of this Court for the purpose of enforcement of the Protective Order in this action.

Sworn and subscribed to
before me this ____ day
of _____, 200__.

Notary Public

My Commission expires: _____

62510_1

EXHIBIT 27

**AMENDMENTS TO THE
FEDERAL RULES OF CIVIL PROCEDURE**

**Rule 16. Pretrial Conferences; Scheduling;
Management**

* * * * *

(b) Scheduling and Planning. Except in categories of actions exempted by district court rule as inappropriate, the district judge, or a magistrate judge when authorized by district court rule, shall, after receiving the report from the parties under Rule 26(f) or after consulting with the attorneys for the parties and any unrepresented parties by a scheduling conference, telephone, mail, or other suitable means, enter a scheduling order that limits the time

- (1)** to join other parties and to amend the pleadings;
- (2)** to file motions; and
- (3)** to complete discovery.

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The scheduling order also may include

- (4) modifications of the times for disclosures under Rules 26(a) and 26(e)(1) and of the extent of discovery to be permitted;
- (5) provisions for disclosure or discovery of electronically stored information;
- (6) any agreements the parties reach for asserting claims of privilege or of protection as trial-preparation material after production;
- (7) the date or dates for conferences before trial, a final pretrial conference, and trial; and
- (8) any other matters appropriate in the circumstances of the case.

The order shall issue as soon as practicable but in any event within 90 days after the appearance of a defendant and within 120 days after the complaint has been served on a defendant. A schedule shall not be

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modified except upon a showing of good cause and by leave of the district judge or, when authorized by local rule, by a magistrate judge.

Committee Note

The amendment to Rule 16(b) is designed to alert the court to the possible need to address the handling of discovery of electronically stored information early in the litigation if such discovery is expected to occur. Rule 26(f) is amended to direct the parties to discuss discovery of electronically stored information if such discovery is contemplated in the action. Form 35 is amended to call for a report to the court about the results of this discussion. In many instances, the court's involvement early in the litigation will help avoid difficulties that might otherwise arise.

Rule 16(b) is also amended to include among the topics that may be addressed in the scheduling order any agreements that the parties reach to facilitate discovery by minimizing the risk of waiver of privilege or work-product protection. Rule 26(f) is amended to add to the discovery plan the parties' proposal for the court to enter a case-management or other order adopting such an agreement. The parties may agree to various arrangements. For example, they may agree to initial provision of requested materials without waiver of privilege or protection to enable the party seeking

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production to designate the materials desired or protection for actual production, with the privilege review of only those materials to follow. Alternatively, they may agree that if privileged or protected information is inadvertently produced, the producing party may by timely notice assert the privilege or protection and obtain return of the materials without waiver. Other arrangements are possible. In most circumstances, a party who receives information under such an arrangement cannot assert that production of the information waived a claim of privilege or of protection as trial-preparation material.

An order that includes the parties' agreement may be helpful in avoiding delay and excessive cost in discovery. See *Manual for Complex Litigation (4th)* § 11.446. Rule 16(b)(6) recognizes the propriety of including such agreements in the court's order. The rule does not provide the court with authority to enter such a case-management or other order without party agreement, or limit the court's authority to act on motion.

Rule 26. General Provisions Governing Discovery; Duty of Disclosure

(a) Required Disclosures; Methods to Discover Additional Matter.

(1) Initial Disclosures. Except in categories of proceedings specified in Rule 26(a)(1)(E), or to the

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extent otherwise stipulated or directed by order, a party must, without awaiting a discovery request, provide to other parties:

(A) the name and, if known, the address and telephone number of each individual likely to have discoverable information that the disclosing party may use to support its claims or defenses, unless solely for impeachment, identifying the subjects of the information;

(B) a copy of, or a description by category and location of, all documents, electronically stored information, and tangible things that are in the possession, custody, or control of the party and that the disclosing party may use to support its claims or defenses, unless solely for impeachment;

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(b) Discovery Scope and Limits. Unless otherwise limited by order of the court in accordance with these rules, the scope of discovery is as follows:

* * * * *

(2) Limitations.

(A) By order, the court may alter the limits in these rules on the number of depositions and interrogatories or the length of depositions under Rule 30. By order or local rule, the court may also limit the number of requests under Rule 36.

(B) A party need not provide discovery of electronically stored information from sources that the party identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the party from whom discovery is sought

FEDERAL RULES OF CIVIL PROCEDURE 7
must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(C) The frequency or extent of use of the discovery methods otherwise permitted under these rules and by any local rule shall be limited by the court if it determines that: (i) the discovery sought is unreasonably cumulative or duplicative, or is obtainable from some other source that is more convenient, less burdensome, or less expensive; (ii) the party seeking discovery has had ample opportunity by

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discovery in the action to obtain the information sought; or (iii) the burden or expense of the proposed discovery outweighs its likely benefit, taking into account the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues. The court may act upon its own initiative after reasonable notice or pursuant to a motion under Rule 26(c).

(5) Claims of Privilege or Protection of Trial-Preparation Materials.

(A) Information Withheld. When a party withholds information otherwise discoverable under these rules by claiming that it is privileged or subject to protection as trial-

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preparation material, the party shall make the claim expressly and shall describe the nature of the documents, communications, or things not produced or disclosed in a manner that, without revealing information itself privileged or protected, will enable other parties to assess the applicability of the privilege or protection.

(B) Information Produced. If information is produced in discovery that is subject to a claim of privilege or of protection as trial-preparation material, the party making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has and may not use or disclose the information until the claim is resolved. A

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receiving party may promptly present the information to the court under seal for a determination of the claim. If the receiving party disclosed the information before being notified, it must take reasonable steps to retrieve it. The producing party must preserve the information until the claim is resolved.

* * * * *

(f) Conference of Parties; Planning for Discovery.

Except in categories of proceedings exempted from initial disclosure under Rule 26(a)(1)(E) or when otherwise ordered, the parties must, as soon as practicable and in any event at least 21 days before a scheduling conference is held or a scheduling order is due under Rule 16(b), confer to consider the nature and basis of their claims and defenses and the possibilities for a prompt settlement or resolution of

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the case, to make or arrange for the disclosures required by Rule 26(a)(1), to discuss any issues relating to preserving discoverable information, and to develop a proposed discovery plan that indicates the parties' views and proposals concerning:

- (1) what changes should be made in the timing, form, or requirement for disclosures under Rule 26(a), including a statement as to when disclosures under Rule 26(a)(1) were made or will be made;
- (2) the subjects on which discovery may be needed, when discovery should be completed, and whether discovery should be conducted in phases or be limited to or focused upon particular issues;
- (3) any issues relating to disclosure or discovery of electronically stored information, including the form or forms in which it should be produced;

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- (4) any issues relating to claims of privilege or of protection as trial-preparation material, including — if the parties agree on a procedure to assert such claims after production — whether to ask the court to include their agreement in an order;
- (5) what changes should be made in the limitations on discovery imposed under these rules or by local rule, and what other limitations should be imposed; and
- (6) any other orders that should be entered by the court under Rule 26(c) or under Rule 16(b) and (c).

* * * * *

Committee Note

Subdivision (a). Rule 26(a)(1)(B) is amended to parallel Rule 34(a) by recognizing that a party must disclose electronically stored information as well as documents that it may use to support its claims or defenses. The term “electronically stored information” has the same broad meaning in Rule 26(a)(1) as in Rule 34(a). This amendment is consistent with the 1993 addition of Rule 26(a)(1)(B). The term “data

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compilations" is deleted as unnecessary because it is a subset of both documents and electronically stored information.

Subdivision (b)(2). The amendment to Rule 26(b)(2) is designed to address issues raised by difficulties in locating, retrieving, and providing discovery of some electronically stored information. Electronic storage systems often make it easier to locate and retrieve information. These advantages are properly taken into account in determining the reasonable scope of discovery in a particular case. But some sources of electronically stored information can be accessed only with substantial burden and cost. In a particular case, these burdens and costs may make the information on such sources not reasonably accessible.

It is not possible to define in a rule the different types of technological features that may affect the burdens and costs of accessing electronically stored information. Information systems are designed to provide ready access to information used in regular ongoing activities. They also may be designed so as to provide ready access to information that is not regularly used. But a system may retain information on sources that are accessible only by incurring substantial burdens or costs. Subparagraph (B) is added to regulate discovery from such sources.

Under this rule, a responding party should produce electronically stored information that is relevant, not privileged, and reasonably accessible, subject to the (b)(2)(C) limitations that apply to all

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discovery. The responding party must also identify, by category or type, the sources containing potentially responsive information that it is neither searching nor producing. The identification should, to the extent possible, provide enough detail to enable the requesting party to evaluate the burdens and costs of providing the discovery and the likelihood of finding responsive information on the identified sources.

A party's identification of sources of electronically stored information as not reasonably accessible does not relieve the party of its common-law or statutory duties to preserve evidence. Whether a responding party is required to preserve unsearched sources of potentially responsive information that it believes are not reasonably accessible depends on the circumstances of each case. It is often useful for the parties to discuss this issue early in discovery.

The volume of — and the ability to search — much electronically stored information means that in many cases the responding party will be able to produce information from reasonably accessible sources that will fully satisfy the parties' discovery needs. In many circumstances the requesting party should obtain and evaluate the information from such sources before insisting that the responding party search and produce information contained on sources that are not reasonably accessible. If the requesting party continues to seek discovery of information from sources identified as not reasonably accessible, the parties should discuss the burdens and costs of accessing and retrieving the information, the needs that may establish good cause for requiring all or part

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of the requested discovery even if the information sought is not reasonably accessible, and conditions on obtaining and producing the information that may be appropriate.

If the parties cannot agree whether, or on what terms, sources identified as not reasonably accessible should be searched and discoverable information produced, the issue may be raised either by a motion to compel discovery or by a motion for a protective order. The parties must confer before bringing either motion. If the parties do not resolve the issue and the court must decide, the responding party must show that the identified sources of information are not reasonably accessible because of undue burden or cost. The requesting party may need discovery to test this assertion. Such discovery might take the form of requiring the responding party to conduct a sampling of information contained on the sources identified as not reasonably accessible; allowing some form of inspection of such sources; or taking depositions of witnesses knowledgeable about the responding party's information systems.

Once it is shown that a source of electronically stored information is not reasonably accessible, the requesting party may still obtain discovery by showing good cause, considering the limitations of Rule 26(b)(2)(C), that balance the costs and potential benefits of discovery. The decision whether to require a responding party to search for and produce information that is not reasonably accessible depends not only on the burdens and costs of doing so, but also, on whether those burdens and

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costs can be justified in the circumstances of the case. Appropriate considerations may include: (1) the specificity of the discovery request; (2) the quantity of information available from other and more easily accessed sources; (3) the failure to produce relevant information that seems likely to have existed but is no longer available on more easily accessed sources; (4) the likelihood of finding relevant, responsive information that cannot be obtained from other, more easily accessed sources; (5) predictions as to the importance and usefulness of the further information; (6) the importance of the issues at stake in the litigation; and (7) the parties' resources.

The responding party has the burden as to one aspect of the inquiry — whether the identified sources are not reasonably accessible in light of the burdens and costs required to search for, retrieve, and produce whatever responsive information may be found. The requesting party has the burden of showing that its need for the discovery outweighs the burdens and costs of locating, retrieving, and producing the information. In some cases, the court will be able to determine whether the identified sources are not reasonably accessible and whether the requesting party has shown good cause for some or all of the discovery, consistent with the limitations of Rule 26(b)(2)(C), through a single proceeding or presentation. The good-cause determination, however, may be complicated because the court and parties may know little about what information the sources identified as not reasonably accessible might contain, whether it is relevant, or how valuable it may be to the litigation. In such cases, the parties may need some

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focused discovery, which may include sampling of the sources, to learn more about what burdens and costs are involved in accessing the information, what the information consists of, and how valuable it is for the litigation in light of information that can be obtained by exhausting other opportunities for discovery.

The good-cause inquiry and consideration of the Rule 26(b)(2)(C) limitations are coupled with the authority to set conditions for discovery. The conditions may take the form of limits on the amount, type, or sources of information required to be accessed and produced. The conditions may also include payment by the requesting party of part or all of the reasonable costs of obtaining information from sources that are not reasonably accessible. A requesting party's willingness to share or bear the access costs may be weighed by the court in determining whether there is good cause. But the producing party's burdens in reviewing the information for relevance and privilege may weigh against permitting the requested discovery.

The limitations of Rule 26(b)(2)(C) continue to apply to all discovery of electronically stored information, including that stored on reasonably accessible electronic sources.

Subdivision (b)(5). The Committee has repeatedly been advised that the risk of privilege waiver, and the work necessary to avoid it, add to the costs and delay of discovery. When the review is of electronically stored information, the risk of waiver, and the time and effort required to avoid it, can

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increase substantially because of the volume of electronically stored information and the difficulty in ensuring that all information to be produced has in fact been reviewed. Rule 26(b)(5)(A) provides a procedure for a party that has withheld information on the basis of privilege or protection as trial-preparation material to make the claim so that the requesting party can decide whether to contest the claim and the court can resolve the dispute. Rule 26(b)(5)(B) is added to provide a procedure for a party to assert a claim of privilege or trial-preparation material protection after information is produced in discovery in the action and, if the claim is contested, permit any party that received the information to present the matter to the court for resolution.

Rule 26(b)(5)(B) does not address whether the privilege or protection that is asserted after production was waived by the production. The courts have developed principles to determine whether, and under what circumstances, waiver results from inadvertent production of privileged or protected information. Rule 26(b)(5)(B) provides a procedure for presenting and addressing these issues. Rule 26(b)(5)(B) works in tandem with Rule 26(f), which is amended to direct the parties to discuss privilege issues in preparing their discovery plan, and which, with amended Rule 16(b), allows the parties to ask the court to include in an order any agreements the parties reach regarding issues of privilege or trial-preparation material protection. Agreements reached under Rule 26(f)(4) and orders including such agreements entered under Rule 16(b)(6) may be considered when a court determines whether a waiver has occurred. Such

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agreements and orders ordinarily control if they adopt procedures different from those in Rule 26(b)(5)(B).

A party asserting a claim of privilege or protection after production must give notice to the receiving party. That notice should be in writing unless the circumstances preclude it. Such circumstances could include the assertion of the claim during a deposition. The notice should be as specific as possible in identifying the information and stating the basis for the claim. Because the receiving party must decide whether to challenge the claim and may sequester the information and submit it to the court for a ruling on whether the claimed privilege or protection applies and whether it has been waived, the notice should be sufficiently detailed so as to enable the receiving party and the court to understand the basis for the claim and to determine whether waiver has occurred. Courts will continue to examine whether a claim of privilege or protection was made at a reasonable time when delay is part of the waiver determination under the governing law.

After receiving notice, each party that received the information must promptly return, sequester, or destroy the information and any copies it has. The option of sequestering or destroying the information is included in part because the receiving party may have incorporated the information in protected trial-preparation materials. No receiving party may use or disclose the information pending resolution of the privilege claim. The receiving party may present to the court the questions whether the information is privileged or protected as trial-preparation material,

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and whether the privilege or protection has been waived. If it does so, it must provide the court with the grounds for the privilege or protection specified in the producing party's notice, and serve all parties. In presenting the question, the party may use the content of the information only to the extent permitted by the applicable law of privilege, protection for trial-preparation material, and professional responsibility.

If a party disclosed the information to nonparties before receiving notice of a claim of privilege or protection as trial-preparation material, it must take reasonable steps to retrieve the information and to return it, sequester it until the claim is resolved, or destroy it.

Whether the information is returned or not, the producing party must preserve the information pending the court's ruling on whether the claim of privilege or of protection is properly asserted and whether it was waived. As with claims made under Rule 26(b)(5)(A), there may be no ruling if the other parties do not contest the claim.

Subdivision (f). Rule 26(f) is amended to direct the parties to discuss discovery of electronically stored information during their discovery-planning conference. The rule focuses on "issues relating to disclosure or discovery of electronically stored information"; the discussion is not required in cases not involving electronic discovery, and the amendment imposes no additional requirements in those cases. When the parties do anticipate disclosure or discovery of electronically stored information, discussion at the

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outset may avoid later difficulties or ease their resolution.

When a case involves discovery of electronically stored information, the issues to be addressed during the Rule 26(f) conference depend on the nature and extent of the contemplated discovery and of the parties' information systems. It may be important for the parties to discuss those systems, and accordingly important for counsel to become familiar with those systems before the conference. With that information, the parties can develop a discovery plan that takes into account the capabilities of their computer systems. In appropriate cases identification of, and early discovery from, individuals with special knowledge of a party's computer systems may be helpful.

The particular issues regarding electronically stored information that deserve attention during the discovery planning stage depend on the specifics of the given case. See *Manual for Complex Litigation (4th)* § 40.25(2) (listing topics for discussion in a proposed order regarding meet-and-confer sessions). For example, the parties may specify the topics for such discovery and the time period for which discovery will be sought. They may identify the various sources of such information within a party's control that should be searched for electronically stored information. They may discuss whether the information is reasonably accessible to the party that has it, including the burden or cost of retrieving and reviewing the information. See Rule 26(b)(2)(B). Rule 26(f)(3) explicitly directs the parties to discuss the form or

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forms in which electronically stored information might be produced. The parties may be able to reach agreement on the forms of production, making discovery more efficient. Rule 34(b) is amended to permit a requesting party to specify the form or forms in which it wants electronically stored information produced. If the requesting party does not specify a form, Rule 34(b) directs the responding party to state the forms it intends to use in the production. Early discussion of the forms of production may facilitate the application of Rule 34(b) by allowing the parties to determine what forms of production will meet both parties' needs. Early identification of disputes over the forms of production may help avoid the expense and delay of searches or productions using inappropriate forms.

Rule 26(f) is also amended to direct the parties to discuss any issues regarding preservation of discoverable information during their conference as they develop a discovery plan. This provision applies to all sorts of discoverable information, but can be particularly important with regard to electronically stored information. The volume and dynamic nature of electronically stored information may complicate preservation obligations. The ordinary operation of computers involves both the automatic creation and the automatic deletion or overwriting of certain information. Failure to address preservation issues early in the litigation increases uncertainty and raises a risk of disputes.

The parties' discussion should pay particular attention to the balance between the competing needs

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to preserve relevant evidence and to continue routine operations critical to ongoing activities. Complete or broad cessation of a party's routine computer operations could paralyze the party's activities. Cf. *Manual for Complex Litigation (4th)* § 11.422 ("A blanket preservation order may be prohibitively expensive and unduly burdensome for parties dependent on computer systems for their day-to-day operations.") The parties should take account of these considerations in their discussions, with the goal of agreeing on reasonable preservation steps.

The requirement that the parties discuss preservation does not imply that courts should routinely enter preservation orders. A preservation order entered over objections should be narrowly tailored. Ex parte preservation orders should issue only in exceptional circumstances.

Rule 26(f) is also amended to provide that the parties should discuss any issues relating to assertions of privilege or of protection as trial-preparation materials, including whether the parties can facilitate discovery by agreeing on procedures for asserting claims of privilege or protection after production and whether to ask the court to enter an order that includes any agreement the parties reach. The Committee has repeatedly been advised about the discovery difficulties that can result from efforts to guard against waiver of privilege and work-product protection. Frequently parties find it necessary to spend large amounts of time reviewing materials requested through discovery to avoid waiving privilege. These efforts are necessary because materials subject

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to a claim of privilege or protection are often difficult to identify. A failure to withhold even one such item may result in an argument that there has been a waiver of privilege as to all other privileged materials on that subject matter. Efforts to avoid the risk of waiver can impose substantial costs on the party producing the material and the time required for the privilege review can substantially delay access for the party seeking discovery.

These problems often become more acute when discovery of electronically stored information is sought. The volume of such data, and the informality that attends use of e-mail and some other types of electronically stored information, may make privilege determinations more difficult, and privilege review correspondingly more expensive and time consuming. Other aspects of electronically stored information pose particular difficulties for privilege review. For example, production may be sought of information automatically included in electronic files but not apparent to the creator or to readers. Computer programs may retain draft language, editorial comments, and other deleted matter (sometimes referred to as "embedded data" or "embedded edits") in an electronic file but not make them apparent to the reader. Information describing the history, tracking, or management of an electronic file (sometimes called "metadata") is usually not apparent to the reader viewing a hard copy or a screen image. Whether this information should be produced may be among the topics discussed in the Rule 26(f) conference. If it is, it may need to be reviewed to ensure that no privileged

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information is included, further complicating the task of privilege review.

Parties may attempt to minimize these costs and delays by agreeing to protocols that minimize the risk of waiver. They may agree that the responding party will provide certain requested materials for initial examination without waiving any privilege or protection — sometimes known as a “quick peek.” The requesting party then designates the documents it wishes to have actually produced. This designation is the Rule 34 request. The responding party then responds in the usual course, screening only those documents actually requested for formal production and asserting privilege claims as provided in Rule 26(b)(5)(A). On other occasions, parties enter agreements — sometimes called “clawback agreements” — that production without intent to waive privilege or protection should not be a waiver so long as the responding party identifies the documents mistakenly produced, and that the documents should be returned under those circumstances. Other voluntary arrangements may be appropriate depending on the circumstances of each litigation. In most circumstances, a party who receives information under such an arrangement cannot assert that production of the information waived a claim of privilege or of protection as trial-preparation material.

Although these agreements may not be appropriate for all cases, in certain cases they can facilitate prompt and economical discovery by reducing delay before the discovering party obtains access to documents, and by reducing the cost and burden of

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review by the producing party. A case-management or other order including such agreements may further facilitate the discovery process. Form 35 is amended to include a report to the court about any agreement regarding protections against inadvertent forfeiture or waiver of privilege or protection that the parties have reached, and Rule 16(b) is amended to recognize that the court may include such an agreement in a case-management or other order. If the parties agree to entry of such an order, their proposal should be included in the report to the court.

Rule 26(b)(5)(B) is added to establish a parallel procedure to assert privilege or protection as trial-preparation material after production, leaving the question of waiver to later determination by the court.

Rule 33. Interrogatories to Parties

(d) Option to Produce Business Records. Where the answer to an interrogatory may be derived or ascertained from the business records, including electronically stored information, of the party upon whom the interrogatory has been served or from an examination, audit or inspection of such business

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records, including a compilation, abstract or summary thereof, and the burden of deriving or ascertaining the answer is substantially the same for the party serving the interrogatory as for the party served, it is a sufficient answer to such interrogatory to specify the records from which the answer may be derived or ascertained and to afford to the party serving the interrogatory reasonable opportunity to examine, audit or inspect such records and to make copies, compilations, abstracts, or summaries. A specification shall be in sufficient detail to permit the interrogating party to locate and to identify, as readily as can the party served, the records from which the answer may be ascertained.

Committee Note

Rule 33(d) is amended to parallel Rule 34(a) by recognizing the importance of electronically stored information. The term "electronically stored information" has the same broad meaning in Rule

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33(d) as in Rule 34(a). Much business information is stored only in electronic form; the Rule 33(d) option should be available with respect to such records as well.

Special difficulties may arise in using electronically stored information, either due to its form or because it is dependent on a particular computer system. Rule 33(d) allows a responding party to substitute access to documents or electronically stored information for an answer only if the burden of deriving the answer will be substantially the same for either party. Rule 33(d) states that a party electing to respond to an interrogatory by providing electronically stored information must ensure that the interrogating party can locate and identify it "as readily as can the party served," and that the responding party must give the interrogating party a "reasonable opportunity to examine, audit, or inspect" the information. Depending on the circumstances, satisfying these provisions with regard to electronically stored information may require the responding party to provide some combination of technical support, information on application software, or other assistance. The key question is whether such support enables the interrogating party to derive or ascertain the answer from the electronically stored information as readily as the responding party. A party that wishes to invoke Rule 33(d) by specifying electronically stored information may be required to provide direct access to its electronic information system, but only if that is necessary to afford the requesting party an adequate opportunity to derive or ascertain the answer to the interrogatory. In that situation, the responding

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party's need to protect sensitive interests of confidentiality or privacy may mean that it must derive or ascertain and provide the answer itself rather than invoke Rule 33(d).

Rule 34. Production of Documents, Electronically Stored Information, and Things and Entry Upon Land for Inspection and Other Purposes

(a) **Scope.** Any party may serve on any other party a request (1) to produce and permit the party making the request, or someone acting on the requestor's behalf, to inspect, copy, test, or sample any designated documents or electronically stored information — including writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any medium from which information can be obtained — translated, if necessary, by the respondent into reasonably usable form, or to inspect, copy, test, or sample any designated tangible things which constitute or contain matters within the scope of Rule 26(b) and which are

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in the possession, custody or control of the party upon whom the request is served; or (2) to permit entry upon designated land or other property in the possession or control of the party upon whom the request is served for the purpose of inspection and measuring, surveying, photographing, testing, or sampling the property or any designated object or operation thereon, within the scope of Rule 26(b).

(b) Procedure. The request shall set forth, either by individual item or by category, the items to be inspected, and describe each with reasonable particularity. The request shall specify a reasonable time, place, and manner of making the inspection and performing the related acts. The request may specify the form or forms in which electronically stored information is to be produced. Without leave of court

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or written stipulation, a request may not be served before the time specified in Rule 26(d).

The party upon whom the request is served shall serve a written response within 30 days after the service of the request. A shorter or longer time may be directed by the court or, in the absence of such an order, agreed to in writing by the parties, subject to Rule 29. The response shall state, with respect to each item or category, that inspection and related activities will be permitted as requested, unless the request is objected to, including an objection to the requested form or forms for producing electronically stored information, stating the reasons for the objection. If objection is made to part of an item or category, the part shall be specified and inspection permitted of the remaining parts. If objection is made to the requested form or forms for producing

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electronically stored information — or if no form was specified in the request — the responding party must state the form or forms it intends to use. The party submitting the request may move for an order under Rule 37(a) with respect to any objection to or other failure to respond to the request or any part thereof, or any failure to permit inspection as requested.

Unless the parties otherwise agree, or the court otherwise orders:

- (i) a party who produces documents for inspection shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the request;
- (ii) if a request does not specify the form or forms for producing electronically stored information, a responding party must produce the information in a form or forms in which it is ordinarily maintained

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or in a form or forms that are reasonably usable;
and

(iii) a party need not produce the same electronically stored information in more than one form.

* * * * *

Committee Note

Subdivision (a). As originally adopted, Rule 34 focused on discovery of "documents" and "things." In 1970, Rule 34(a) was amended to include discovery of data compilations, anticipating that the use of computerized information would increase. Since then, the growth in electronically stored information and in the variety of systems for creating and storing such information has been dramatic. Lawyers and judges interpreted the term "documents" to include electronically stored information because it was obviously improper to allow a party to evade discovery obligations on the basis that the label had not kept pace with changes in information technology. But it has become increasingly difficult to say that all forms of electronically stored information, many dynamic in nature, fit within the traditional concept of a "document." Electronically stored information may exist in dynamic databases and other forms far different from fixed expression on paper. Rule 34(a) is amended to confirm that discovery of electronically

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stored information stands on equal footing with discovery of paper documents. The change clarifies that Rule 34 applies to information that is fixed in a tangible form and to information that is stored in a medium from which it can be retrieved and examined. At the same time, a Rule 34 request for production of "documents" should be understood to encompass, and the response should include, electronically stored information unless discovery in the action has clearly distinguished between electronically stored information and "documents."

Discoverable information often exists in both paper and electronic form, and the same or similar information might exist in both. The items listed in Rule 34(a) show different ways in which information may be recorded or stored. Images, for example, might be hard-copy documents or electronically stored information. The wide variety of computer systems currently in use, and the rapidity of technological change, counsel against a limiting or precise definition of electronically stored information. Rule 34(a)(1) is expansive and includes any type of information that is stored electronically. A common example often sought in discovery is electronic communications, such as e-mail. The rule covers — either as documents or as electronically stored information — information "stored in any medium," to encompass future developments in computer technology. Rule 34(a)(1) is intended to be broad enough to cover all current types of computer-based information, and flexible enough to encompass future changes and developments.

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References elsewhere in the rules to "electronically stored information" should be understood to invoke this expansive approach. A companion change is made to Rule 33(d), making it explicit that parties choosing to respond to an interrogatory by permitting access to responsive records may do so by providing access to electronically stored information. More generally, the term used in Rule 34(a)(1) appears in a number of other amendments, such as those to Rules 26(a)(1), 26(b)(2), 26(b)(5)(B), 26(f), 34(b), 37(f), and 45. In each of these rules, electronically stored information has the same broad meaning it has under Rule 34(a)(1). References to "documents" appear in discovery rules that are not amended, including Rules 30(f), 36(a), and 37(c)(2). These references should be interpreted to include electronically stored information as circumstances warrant.

The term "electronically stored information" is broad, but whether material that falls within this term should be produced, and in what form, are separate questions that must be addressed under Rules 26(b), 26(c), and 34(b).

The Rule 34(a) requirement that, if necessary, a party producing electronically stored information translate it into reasonably usable form does not address the issue of translating from one human language to another. *See In re Puerto Rico Elect. Power Auth.*, 687 F.2d 501, 504-510 (1st Cir. 1989).

Rule 34(a)(1) is also amended to make clear that parties may request an opportunity to test or sample

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materials sought under the rule in addition to inspecting and copying them. That opportunity may be important for both electronically stored information and hard-copy materials. The current rule is not clear that such testing or sampling is authorized; the amendment expressly permits it. As with any other form of discovery, issues of burden and intrusiveness raised by requests to test or sample can be addressed under Rules 26(b)(2) and 26(c). Inspection or testing of certain types of electronically stored information or of a responding party's electronic information system may raise issues of confidentiality or privacy. The addition of testing and sampling to Rule 34(a) with regard to documents and electronically stored information is not meant to create a routine right of direct access to a party's electronic information system, although such access might be justified in some circumstances. Courts should guard against undue intrusiveness resulting from inspecting or testing such systems.

Rule 34(a)(1) is further amended to make clear that tangible things must — like documents and land sought to be examined — be designated in the request.

Subdivision (b). Rule 34(b) provides that a party must produce documents as they are kept in the usual course of business or must organize and label them to correspond with the categories in the discovery request. The production of electronically stored information should be subject to comparable requirements to protect against deliberate or inadvertent production in ways that raise unnecessary obstacles for the requesting party. Rule 34(b) is

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amended to ensure similar protection for electronically stored information.

The amendment to Rule 34(b) permits the requesting party to designate the form or forms in which it wants electronically stored information produced. The form of production is more important to the exchange of electronically stored information than of hard-copy materials, although a party might specify hard copy as the requested form. Specification of the desired form or forms may facilitate the orderly, efficient, and cost-effective discovery of electronically stored information. The rule recognizes that different forms of production may be appropriate for different types of electronically stored information. Using current technology, for example, a party might be called upon to produce word processing documents, e-mail messages, electronic spreadsheets, different image or sound files, and material from databases. Requiring that such diverse types of electronically stored information all be produced in the same form could prove impossible, and even if possible could increase the cost and burdens of producing and using the information. The rule therefore provides that the requesting party may ask for different forms of production for different types of electronically stored information.

The rule does not require that the requesting party choose a form or forms of production. The requesting party may not have a preference. In some cases, the requesting party may not know what form the producing party uses to maintain its electronically stored information, although Rule 26(f)(3) is amended

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to call for discussion of the form of production in the parties' prediscovery conference.

The responding party also is involved in determining the form of production. In the written response to the production request that Rule 34 requires, the responding party must state the form it intends to use for producing electronically stored information if the requesting party does not specify a form or if the responding party objects to a form that the requesting party specifies. Stating the intended form before the production occurs may permit the parties to identify and seek to resolve disputes before the expense and work of the production occurs. A party that responds to a discovery request by simply producing electronically stored information in a form of its choice, without identifying that form in advance of the production in the response required by Rule 34(b), runs a risk that the requesting party can show that the produced form is not reasonably usable and that it is entitled to production of some or all of the information in an additional form. Additional time might be required to permit a responding party to assess the appropriate form or forms of production.

If the requesting party is not satisfied with the form stated by the responding party, or if the responding party has objected to the form specified by the requesting party, the parties must meet and confer under Rule 37(a)(2)(B) in an effort to resolve the matter before the requesting party can file a motion to compel. If they cannot agree and the court resolves the dispute, the court is not limited to the forms initially chosen by the requesting party, stated by the

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responding party, or specified in this rule for situations in which there is no court order or party agreement.

If the form of production is not specified by party agreement or court order, the responding party must produce electronically stored information either in a form or forms in which it is ordinarily maintained or in a form or forms that are reasonably usable. Rule 34(a) requires that, if necessary, a responding party "translate" information it produces into a "reasonably usable" form. Under some circumstances, the responding party may need to provide some reasonable amount of technical support, information on application software, or other reasonable assistance to enable the requesting party to use the information. The rule does not require a party to produce electronically stored information in the form in which it is ordinarily maintained, as long as it is produced in a reasonably usable form. But the option to produce in a reasonably usable form does not mean that a responding party is free to convert electronically stored information from the form in which it is ordinarily maintained to a different form that makes it more difficult or burdensome for the requesting party to use the information efficiently in the litigation. If the responding party ordinarily maintains the information it is producing in a way that makes it searchable by electronic means, the information should not be produced in a form that removes or significantly degrades this feature.

Some electronically stored information may be ordinarily maintained in a form that is not reasonably

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usable by any party. One example is "legacy" data that can be used only by superseded systems. The questions whether a producing party should be required to convert such information to a more usable form, or should be required to produce it at all, should be addressed under Rule 26(b)(2)(B).

Whether or not the requesting party specified the form of production, Rule 34(b) provides that the same electronically stored information ordinarily need be produced in only one form.

Rule 37. Failure to Make Disclosures or Cooperate in Discovery; Sanctions

(f) Electronically Stored Information. Absent exceptional circumstances, a court may not impose sanctions under these rules on a party for failing to provide electronically stored information lost as a result of the routine, good-faith operation of an electronic information system.

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Committee Note

Subdivision (f). Subdivision (f) is new. It focuses on a distinctive feature of computer operations, the routine alteration and deletion of information that attends ordinary use. Many steps essential to computer operation may alter or destroy information, for reasons that have nothing to do with how that information might relate to litigation. As a result, the ordinary operation of computer systems creates a risk that a party may lose potentially discoverable information without culpable conduct on its part. Under Rule 37(f), absent exceptional circumstances, sanctions cannot be imposed for loss of electronically stored information resulting from the routine, good-faith operation of an electronic information system.

Rule 37(f) applies only to information lost due to the "routine operation of an electronic information system" — the ways in which such systems are generally designed, programmed, and implemented to meet the party's technical and business needs. The "routine operation" of computer systems includes the alteration and overwriting of information, often without the operator's specific direction or awareness, a feature with no direct counterpart in hard-copy documents. Such features are essential to the operation of electronic information systems.

Rule 37(f) applies to information lost due to the routine operation of an information system only if the operation was in good faith. Good faith in the routine operation of an information system may involve a

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party's intervention to modify or suspend certain features of that routine operation to prevent the loss of information, if that information is subject to a preservation obligation. A preservation obligation may arise from many sources, including common law, statutes, regulations, or a court order in the case. The good faith requirement of Rule 37(f) means that a party is not permitted to exploit the routine operation of an information system to thwart discovery obligations by allowing that operation to continue in order to destroy specific stored information that it is required to preserve. When a party is under a duty to preserve information because of pending or reasonably anticipated litigation, intervention in the routine operation of an information system is one aspect of what is often called a "litigation hold." Among the factors that bear on a party's good faith in the routine operation of an information system are the steps the party took to comply with a court order in the case or party agreement requiring preservation of specific electronically stored information.

Whether good faith would call for steps to prevent the loss of information on sources that the party believes are not reasonably accessible under Rule 26(b)(2) depends on the circumstances of each case. One factor is whether the party reasonably believes that the information on such sources is likely to be discoverable and not available from reasonably accessible sources.

The protection provided by Rule 37(f) applies only to sanctions "under these rules." It does not

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affect other sources of authority to impose sanctions or rules of professional responsibility.

This rule restricts the imposition of "sanctions." It does not prevent a court from making the kinds of adjustments frequently used in managing discovery if a party is unable to provide relevant responsive information. For example, a court could order the responding party to produce an additional witness for deposition, respond to additional interrogatories, or make similar attempts to provide substitutes or alternatives for some or all of the lost information.

Rule 45. Subpoena

(a) Form; Issuance.

(1) Every subpoena shall

(A) state the name of the court from which it is issued; and

(B) state the title of the action, the name of the court in which it is pending, and its civil action number; and

(C) command each person to whom it is directed to attend and give testimony or to produce and permit inspection, copying, testing,

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or sampling of designated books, documents,
electronically stored information, or tangible
things in the possession, custody or control of
that person, or to permit inspection of premises,
at a time and place therein specified; and
(D) set forth the text of subdivisions (c) and (d)
of this rule.

A command to produce evidence or to permit
inspection, copying, testing, or sampling may be joined
with a command to appear at trial or hearing or at
deposition, or may be issued separately. A subpoena
may specify the form or forms in which electronically
stored information is to be produced.

(2) A subpoena must issue as follows:

* * * * *

(C) for production, inspection, copying, testing,
or sampling, if separate from a subpoena

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commanding a person's attendance, from the
court for the district where the production or
inspection is to be made.

(3) The clerk shall issue a subpoena, signed but
otherwise in blank, to a party requesting it, who
shall complete it before service. An attorney as
officer of the court may also issue and sign a
subpoena on behalf of

(A) a court in which the attorney is authorized
to practice; or

(B) a court for a district in which a deposition
or production is compelled by the subpoena, if
the deposition or production pertains to an
action pending in a court in which the attorney
is authorized to practice.

(b) Service.

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(1) A subpoena may be served by any person who is not a party and is not less than 18 years of age. Service of a subpoena upon a person named therein shall be made by delivering a copy thereof to such person and, if the person's attendance is commanded, by tendering to that person the fees for one day's attendance and the mileage allowed by law. When the subpoena is issued on behalf of the United States or an officer or agency thereof, fees and mileage need not be tendered. Prior notice of any commanded production of documents and things or inspection of premises before trial shall be served on each party in the manner prescribed by Rule 5(b).

(2) Subject to the provisions of clause (ii) of subparagraph (c)(3)(A) of this rule, a subpoena may be served at any place within the district of the

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court by which it is issued, or at any place without the district that is within 100 miles of the place of the deposition, hearing, trial, production, inspection, copying, testing, or sampling specified in the subpoena or at any place within the state where a state statute or rule of court permits service of a subpoena issued by a state court of general jurisdiction sitting in the place of the deposition, hearing, trial, production, inspection, copying, testing, or sampling specified in the subpoena. When a statute of the United States provides therefor, the court upon proper application and cause shown may authorize the service of a subpoena at any other place. A subpoena directed to a witness in a foreign country who is a national or resident of the United States shall issue under

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the circumstances and in the manner and be served as provided in Title 28, U.S.C. § 1783.

(3) Proof of service when necessary shall be made by filing with the clerk of the court by which the subpoena is issued a statement of the date and manner of service and of the names of the persons served, certified by the person who made the service.

(c) Protection of Persons Subject to Subpoenas.

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction, which may include, but is not

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limited to, lost earnings and a reasonable attorney's fee.

(2)(A) A person commanded to produce and permit inspection, copying, testing, or sampling of designated electronically stored information, books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.

(B) Subject to paragraph (d)(2) of this rule, a person commanded to produce and permit inspection, copying, testing, or sampling may, within 14 days after service of the subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the

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subpoena written objection to producing any or
all of the designated materials or inspection of
the premises — or to producing electronically
stored information in the form or forms
requested. If objection is made, the party
serving the subpoena shall not be entitled to
inspect, copy, test, or sample the materials or
inspect the premises except pursuant to an
order of the court by which the subpoena was
issued. If objection has been made, the party
serving the subpoena may, upon notice to the
person commanded to produce, move at any
time for an order to compel the production,
inspection, copying, testing, or sampling. Such
an order to compel shall protect any person who
is not a party or an officer of a party from
significant expense resulting from the

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inspection, copying, testing, or sampling
commanded.

(3)(A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it

(i) fails to allow reasonable time for compliance;

(ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c)(3)(B)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held;

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(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) If a subpoena

(i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or

(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or

(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a

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person subject to or affected by the subpoena, quash or modify the subpoena or, if the party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) Duties in Responding to Subpoena.

(1)(A) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

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(B) If a subpoena does not specify the form or forms for producing electronically stored information, a person responding to a subpoena must produce the information in a form or forms in which the person ordinarily maintains it or in a form or forms that are reasonably usable.

(C) A person responding to a subpoena need not produce the same electronically stored information in more than one form.

(D) A person responding to a subpoena need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or to quash, the person from whom discovery is sought must show that the information sought is not reasonably accessible

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because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) (A) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial-preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

(B) If information is produced in response to a subpoena that is subject to a claim of privilege or of protection as trial-preparation material, the

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person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has and may not use or disclose the information until the claim is resolved. A receiving party may promptly present the information to the court under seal for a determination of the claim. If the receiving party disclosed the information before being notified, it must take reasonable steps to retrieve it. The person who produced the information must preserve the information until the claim is resolved.

(e) Contempt. Failure of any person without adequate excuse to obey a subpoena served upon that person may be deemed a contempt of the court from

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which the subpoena issued. An adequate cause for failure to obey exists when a subpoena purports to require a nonparty to attend or produce at a place not within the limits provided by clause (ii) of subparagraph (c)(3)(A).

Committee Note

Rule 45 is amended to conform the provisions for subpoenas to changes in other discovery rules, largely related to discovery of electronically stored information. Rule 34 is amended to provide in greater detail for the production of electronically stored information. Rule 45(a)(1)(C) is amended to recognize that electronically stored information, as defined in Rule 34(a), can also be sought by subpoena. Like Rule 34(b), Rule 45(a)(1) is amended to provide that the subpoena can designate a form or forms for production of electronic data. Rule 45(c)(2) is amended, like Rule 34(b), to authorize the person served with a subpoena to object to the requested form or forms. In addition, as under Rule 34(b), Rule 45(d)(1)(B) is amended to provide that if the subpoena does not specify the form or forms for electronically stored information, the person served with the subpoena must produce electronically stored information in a form or forms in which it is usually maintained or in a form or forms that are reasonably usable. Rule 45(d)(1)(C) is added to provide that the person producing electronically stored information should not have to produce the same

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information in more than one form unless so ordered by the court for good cause.

As with discovery of electronically stored information from parties, complying with a subpoena for such information may impose burdens on the responding person. Rule 45(c) provides protection against undue impositions on nonparties. For example, Rule 45(c)(1) directs that a party serving a subpoena "shall take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena," and Rule 45(c)(2)(B) permits the person served with the subpoena to object to it and directs that an order requiring compliance "shall protect a person who is neither a party nor a party's officer from significant expense resulting from" compliance. Rule 45(d)(1)(D) is added to provide that the responding person need not provide discovery of electronically stored information from sources the party identifies as not reasonably accessible, unless the court orders such discovery for good cause, considering the limitations of Rule 26(b)(2)(C), on terms that protect a nonparty against significant expense. A parallel provision is added to Rule 26(b)(2).

Rule 45(a)(1)(B) is also amended, as is Rule 34(a), to provide that a subpoena is available to permit testing and sampling as well as inspection and copying. As in Rule 34, this change recognizes that on occasion the opportunity to perform testing or sampling may be important, both for documents and for electronically stored information. Because testing or sampling may present particular issues of burden or intrusion for the person served with the subpoena,

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however, the protective provisions of Rule 45(c) should be enforced with vigilance when such demands are made. Inspection or testing of certain types of electronically stored information or of a person's electronic information system may raise issues of confidentiality or privacy. The addition of sampling and testing to Rule 45(a) with regard to documents and electronically stored information is not meant to create a routine right of direct access to a person's electronic information system, although such access might be justified in some circumstances. Courts should guard against undue intrusiveness resulting from inspecting or testing such systems.

Rule 45(d)(2) is amended, as is Rule 26(b)(5), to add a procedure for assertion of privilege or of protection as trial-preparation materials after production. The receiving party may submit the information to the court for resolution of the privilege claim, as under Rule 26(b)(5)(B).

Other minor amendments are made to conform the rule to the changes described above.

Form 35. Report of Parties' Planning Meeting

3. Discovery Plan. The parties jointly propose to the court the following discovery plan: [Use separate

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paragraphs or subparagraphs as necessary if parties
disagree.]

Discovery will be needed on the following
subjects: (brief description of subjects on which
discovery will be needed)

Disclosure or discovery of electronically stored
information should be handled as follows: (brief
description of parties' proposals)

The parties have agreed to an order regarding claims of
privilege or of protection as trial-preparation material
asserted after production, as follows: (brief description
of provisions of proposed order).

All discovery commenced in time to be
completed by _____ (date) _____. [Discovery
on _____ (issue for early discovery) _____ to be
completed by _____ (date) _____.]

EXHIBIT 28

WYETH-AYERTS W RESEARCH

1101 BOYD STREET, PHILADELPHIA, PA 19103-0229 • (215) 399-3710
FAX: (215) 394-2373

Division of American Home Products Corporation

U.S. REGULATORY AFFAIRS

May 16, 1996

**Effexor XR (venlafaxine HCl) Extended Release Capsules
Original NDA (No. 20-699)**

Paul D. Leber, M.D., Director
Division of Neuropharmacological Drug Products (HFD-120)
Center for Drug Evaluation and Research
Attn: Document Control Room
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Leber:

In accordance with 21 CFR 314.50, Wyeth-Ayerst hereby submits a new drug application for Effexor XR (venlafaxine HCl) Extended Release Capsules for the treatment of depression, including depression with associated anxiety. It is also indicated for the relief of symptoms of anxiety in depressed patients with associated anxiety. NDA No. 20-699 and User Fee ID No. 3009 has been preassigned to this application. Effexor XR Extended Release Capsules are a once-a-day treatment for depression that consists of encapsulated spheroids which release venlafaxine by diffusion through a slow dissolving coating mechanism.

Please note that in compliance with 21 CFR 314.50(k)(3) a true copy of the Chemistry, Manufacturing and Controls technical section, plus the application form and summary section of this NDA have been submitted to the Philadelphia District Office of the FDA, the home office for Wyeth-Ayerst Laboratories. The requested certification concerning this field copy plus the certification required under the Generic Drug Enforcement Act of 1992 are contained in Item 15 of this application. A check for 50% of the required application fee (\$102,000) has been submitted to the Pittsburgh postal address designated for user fee payments.

As you are aware, the immediate-release dosage form of venlafaxine, Effexor®, is already approved (NDA No. 20-151) for the treatment of depression. This extended-release formulation of venlafaxine has also been evaluated in controlled clinical studies. The reports of these studies are included in this application.

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Regulatory History

The original IND (No. 41,412) for venlafaxine extended release (ER) capsules was submitted on December 31, 1992. On December 8, 1994, Wyeth-Ayerst submitted a meeting request to discuss our development plan for the extended-release formulation. The December 8 submission informed the Agency that three placebo-controlled studies would be conducted to evaluate safety and efficacy. Agreement was obtained from the Agency that the general scope and design of the planned studies would support the NDA. Additionally, based on a meeting held on May 20, 1994 and subsequent telephone discussions, agreement was reached on our planned clinical pharmacology studies, that no studies in special populations would need to be conducted, and that no additional preclinical studies would need to be performed with the extended release formulation. Wyeth-Ayerst also indicated at that time, that for the Effexor XR package insert, the information for special populations (hepatically impaired, renally impaired, etc.) would be that currently used in the Effexor package insert.

On September 22, 1995, a pre-NDA format meeting document was submitted to the Agency; the meeting was held on November 21, 1995. The primary purpose of the meeting was to discuss the format/content of this NDA as presented in the above document. General agreement was obtained from the Agency that the proposed organization and content of the NDA would be sufficient to meet the Agency's needs.

Controlled Study Designs

Three double-blind, placebo-controlled, Phase 3 clinical studies were conducted with depressed patients to provide evidence of the safety and efficacy of venlafaxine ER for the treatment of depression. Two (208-US and 209-US) of the three Phase 3 studies provide the primary evidence of safety and efficacy. The third study (367-EU) is supportive. A short description of each of these studies follows.

Protocol 600-B-208-US: double-blind, flexible-dose, twelve-week efficacy study of 75-150 mg venlafaxine ER, 75-150 mg Effexor, and placebo in outpatients with major depression.

Protocol 600-B-209-US: double-blind, flexible-dose, eight-week efficacy study of 75-225 mg venlafaxine ER and placebo in outpatients with major depression.

Protocol 600-B-367-EU: double-blind, fixed-dose, eight-week efficacy study of 75 and 150 mg venlafaxine ER, 20 mg Paxil, and placebo in outpatients with major depression.

NDA Contents

The enclosed NDA contains a chemistry, manufacturing, and controls section, a human pharmacokinetics and a bioavailability section, and clinical and statistical sections. The Effexor NDA is cross-referenced for information on the preclinical pharmacology and toxicology of venlafaxine and the drug substance. As per discussion (December 6, 1995) between Wyeth-Ayerst's Mr. Kenneth R. Bonk and the Agency's Dr. Maryla Guzewska, a Methods Validation package is not included in the submission. Dr. Guzewska recommended that Wyeth-Ayerst provide the Agency with the Methods Validation package after she has completed her review of the chemistry, manufacturing and controls section of the application and any comments provided

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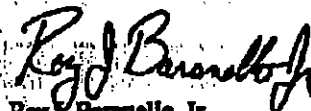
to Wyeth-Ayerst have been addressed. The NDA contents are as follows:

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3	Chemistry, Manufacturing and Controls	2-13
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6	Human Pharmacokinetics and Bioavailability	15-59
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11	Case Report Tabulations	136-220
12	Case Report Forms	221-233
13	Patent and Exclusivity Information	1
15a	Certification for Transmittal of a True Copy of Item 3 to the Philadelphia District Office	1
15b	Certification Required by the Generic Drug Enforcement Act of 1992	1

If you have any questions regarding this submission, please contact our representative,
Mr. Kenneth R. Bonk, at (610) 902-3101.

Sincerely yours,

WYETH-AYERST LABORATORIES



Roy J. Barnello, Jr.
Director, U.S. Regulatory Affairs

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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	Protocol 600-B-144-ER				
	GMR 26761	1.62			

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Protocol 600-B-208-US
GMR 26165 1.63-1.72
- 2) Double-Blind, Placebo-Controlled Study of Venlafaxine ER in Outpatients with Major Depression: Final Report
Protocol 600-B-209-US
GMR 27258 1.73-1.79
- 3) A Randomized, Double-Blind, Placebo-Controlled, Fixed-Dose Study of the Efficacy and Safety of Venlafaxine Extended-Release and Paroxetine in Depressed Outpatients: Final Report
Protocol 600-B-367-EU
GMR 25782 1.80-1.84D

b. Ongoing Studies

- 1) Double-Blind, Placebo-Controlled Study of Venlafaxine ER vs. Fluoxetine in Outpatients with Major Depression
Protocol 600-B-211-US
Progress Report 1.85 1
- 2) A Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of Venlafaxine Extended Release versus Fluoxetine in Depressed Outpatients with Concomitant Anxiety
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Protocol 600-B-365-EU
GMR 25781 1.86-1.88
- b. An Open-Label Evaluation of the Long-Term Safety and Clinical Acceptability of Venlafaxine-Extended Release Capsules in Depressed Outpatients: Interim Report
Protocol 600-B-369-US
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